NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANDOZ INC., Plaintiff, v. UNITED THERAPEUTICS CORPORATION, Defendant.	Case No. 2:19-cv-10170 (BRM) (JSA) **OPINION TEMPORARILY FILED UNDER SEAL**

MARTINOTTI, DISTRICT JUDGE

This matter comes before the Court by way of an Amended Complaint filed by Plaintiff Sandoz Inc. ("Sandoz"), a generic manufacturer and seller of treprostinil, seeking damages for breach of contract against Defendant United Therapeutics Corporation ("UTC"), a brand name manufacturer and seller of treprostinil.[1] The Court held a three-day bench trial beginning on April 29, 2024 and concluding on May 1, 2024. The parties submitted proposed findings of fact and conclusions of law on May 24, 2024. (ECF Nos. 493, 494.) Closing arguments were held on June 4, 2024.[2] The sole issue at trial was Sandoz's damages on its breach of contract claim.

This Opinion constitutes the Court's findings of fact and conclusions of law pursuant to

[1] Treprostinil is a medication used to treat patients with pulmonary arterial hypertension ("PAH"), a disease that causes high blood pressure in the arteries that run from the heart to the lungs. (Stipulation of Facts (ECF No. 445 § 3) ¶¶ 1–2).) PAH is a rare and serious disease affecting a very fragile patient population. (*Id.* ¶ 3.) UTC's Remodulin (treprostinil) Injection ("Remodulin") is the brand name for injected treprostinil. (*Id.* ¶ 5.) When the Court refers to "treprostinil" in the Opinion, it is referring to injected treprostinil unless otherwise specified.

[2] It is not undue praise to note that the parties were well represented by their attorneys; the Court takes this opportunity to thank counsel for their exceptional efforts evident from trial presentation, briefing, and closing arguments.

Federal Rule of Civil Procedure 52(a). The findings of fact are based on the Court's observations and credibility determinations of the witnesses who testified, and a thorough review of all the admissible evidence.

I. BACKGROUND

A. Factual Background[3]

Treprostinil is an injectable medication administered either intravenously or subcutaneously. (ECF No. 445 § 3, ¶ 12.) Both routes of administration rely on continuous infusion via an external infusion pump. (*Id.* ¶ 13.) Subcutaneous administration of treprostinil requires a pump, such as the CADD-MS 3 pump,[4] and a three-milliliter medical cartridge. (ECF No. 322-1 ¶¶ 4, 9–10; ECF No. 336-1 ¶¶ 4, 9–10.) In administering treprostinil, the medication is placed in a disposable medical cartridge that is then loaded into the pump. (ECF No. 320-1 ¶ 23; ECF No. 362-1 ¶ 23.)

1. The 2015 Settlement Agreement

UTC developed and launched Remodulin in 2002. (ECF No. 445 § 3, ¶ 6.) In 2011, Sandoz submitted an abbreviated new drug application ("ANDA") with the Food and Drug Administration ("FDA"), seeking approval to market its generic treprostinil. (*Id.* ¶ 7.) Shortly thereafter, UTC sued Sandoz, contending the generic version infringed on its patent. (ECF No. 320-1 ¶ 5; ECF No.

[3] The factual and procedural background of this matter are well known to the parties and have been recounted by the Court in numerous prior opinions. The following facts were detailed by the Court in the March 30, 2022 Opinion, where the Court addressed summary judgment motions and a motion to exclude an expert report. (ECF Nos. 382, 388.) The Court provides these facts as context of UTC's breach, and why the Court conducted a trial on Sandoz's damages.

[4] The CADD-MS 3 is an infusion pump system that can be used to administer injected treprostinil intravenously or subcutaneously. (*Id.* ¶ 14.) To use the CADD-MS 3 subcutaneously, the treprostinil must be placed in a suitable disposable cartridge, which is then loaded into the CADD-MS 3. (*Id.* ¶ 16.) Without a suitable cartridge, the CADD-MS 3 cannot administer medication subcutaneously to the patient. (*Id.*)

362-1 ¶ 5.) Ultimately, on September 29, 2015, Sandoz and UTC entered into the 2015 Settlement Agreement to resolve the litigation. (ECF No. 445 § 3, ¶ 9.)

Under the 2015 Settlement Agreement, UTC granted Sandoz the right to make and market its generic treprostinil beginning June 26, 2018. (*Id.* ¶ 10.) Pursuant to Section 11(b) of the 2015 Settlement Agreement, UTC agreed "[n]ot to take any action directly or indirectly to prevent, delay, limit, or otherwise restrict the launch, manufacture, use, sale, offer for sale, importation or distribution of the Sandoz ANDA Product in [the United States]." (ECF No. 320-1 ¶ 11; ECF No. 362-1 ¶ 11.) Section 4(l) defines the "Sandoz ANDA Product" as "the treprostinil injection for subcutaneous or intravenous use pharmaceutical products that are described in, and are the subject of, the Sandoz ANDA . . . [but] shall expressly not include . . . any technology associated with any UTC product(s)." (2015 Settlement Agreement (ECF No. 320-8) at 7; ECF No. 362-1 ¶ 84.) Section 15 of the 2015 Settlement Agreement provides:

> UTC . . . shall not, and shall not cause any Third Party to: (a) initiate or otherwise undertake any activity . . . , directly or indirectly, against the Sandoz ANDA or the Sandoz ANDA Product to . . . (ii) interfere with Sandoz's efforts to launch the Sandoz ANDA Product . . . as of the Effective Launch Date under the terms provided by this Agreement.

(ECF No. 320-8 at 15; ECF No. 320-1 ¶ 12; ECF No. 362-1 ¶ 12.)

2. 2016 Supply Agreement

Smiths Medical ASD, Inc. ("Smiths") started developing the CADD-MS 3 in January 2005 and received FDA clearance in November 2005. (*Id.* ¶ 15.) The FDA-cleared manual for the CADD-MS 3, which Smiths published in 2008, stated: "Use only Smiths [] 3 ml Medication Cartridges; other manufacturers' products will not work with the CADD-MS 3 pump." (*Id.*) Smiths sold its CADD-MS 3 pumps and medical cartridges to two specialty pharmacy distributors, Accredo Health Group ("Accredo") and CVS Specialty ("CVS") (collectively, the "Specialty

Pharmacies"), who in turn provided the injectable medication to patients. (ECF No. 320-1 ¶¶ 24–26; ECF No. 362-1 ¶¶ 24–26.)

In 2015, Smiths decided to discontinue making the CADD-MS 3 pump "primarily due to the lack of ongoing availability of critical components from third party suppliers." (ECF No. 322-1 ¶¶ 18–19; ECF No. 336-1 ¶¶ 18–19.) On August 25, 2015, Smiths sent an end-of-life notice for the CADD-MS 3 pump to the Specialty Pharmacies dispensing treprostinil to patients. (ECF No. 322-1 ¶ 21; ECF No. 336-1 ¶ 21.) By October 2015, Smiths shut down its manufacturing line for CADD-MS 3 pumps. (ECF No. 322-1 ¶ 24; ECF No. 336-1 ¶ 24.)

Smiths discussed the discontinuation of the CADD-MS 3 pump with UTC before making the announcement. (ECF No. 322-1 ¶ 28; ECF No. 336-1 ¶ 28.) UTC was concerned there may not be delivery platforms available for commercial use by the time Smiths exhausted its remaining supply of CADD-MS 3 pumps. (ECF No. 322-1 ¶ 34; ECF No. 336-1 ¶ 34.) Eventually, UTC and Smiths agreed to restart production and develop a partially updated version of the CADD-MS 3 pumps. (ECF No. 322-1 ¶ 39; ECF No. 336-1 ¶ 39.)

In March 2016, UTC and Smiths executed a supply agreement for the CADD-MS 3 pumps ("2016 Supply Agreement"). (ECF No. 322-1 ¶ 45; ECF No. 336-1 ¶ 45.) Under the 2016 Supply Agreement, Smiths committed to producing 7,000 CADD-MS 3 pumps and 1.6 million cartridges. (*Id.*) UTC agreed to pay $2.5 million immediately, and a total of $23 million for the pumps and $4 million for the cartridges. (*Id.*)

In November and December 2017, because UTC effectively became the owner of all remaining CADD-MS 3 pumps pursuant to the 2016 Supply Agreement, UTC sought to directly contract with the Specialty Pharmacies to distribute the CADD-MS 3 pumps it purchased from Smiths. (ECF No. 322-1 ¶ 77; ECF No. 336-1 ¶ 77.) The agreement between UTC and the

Specialty Pharmacies provided the Specialty Pharmacies would serve as non-exclusive distributors of the pumps "solely for supplying patients who have been dispensed Remodulin." (*Id.*)

3. 2017 Amended Supply Agreement

In January 2017, Smiths informed UTC that customers had been buying large quantities of cartridges for use with drugs other than Remodulin. (ECF No. 322-1 ¶ 62; ECF No. 336-1 ¶ 62.) In February 2017, UTC advised Smiths it wished to amend the arrangement with the cartridges. (ECF No. 322-1 ¶ 66; ECF No. 336-1 ¶ 66.) Smiths did not agree to police how the Specialty Pharmacies used cartridges but committed to seek an agreement from the Specialty Pharmacies to use the cartridges for Remodulin only. (ECF No. 322-1 ¶ 73; ECF No. 336-1 ¶ 73.)

In July 2017, UTC and Smiths entered into a second amended agreement to the 2016 Supply Agreement ("2017 Amended Supply Agreement"). (ECF No. 322-1 ¶ 71; ECF No. 336-1 ¶ 71.) Under the 2017 Amended Supply Agreement, Smiths agreed "to use commercially reasonable efforts to amend its existing agreements with [the Specialty Pharmacies] to include a requirement that Cartridges sold . . . by Smiths . . . be used only with Remodulin." (ECF No. 322-1 ¶ 73; ECF No. 336-1 ¶ 73.) To that end, Smiths sent the Specialty Pharmacies draft agreements to restrict cartridges to Remodulin only. (ECF No. 322-1 ¶ 79; ECF No. 336-1 ¶ 79.) Smiths also agreed under the 2017 Amended Supply Agreement to "provide enhanced reporting to UT[C] regarding its manufacturing, inventory, purchases and sale of cartridges" on a monthly basis. (ECF No. 322-1 ¶ 72; ECF No. 336-1 ¶ 72.)

In January 2018, UTC asked Smiths for an update on the agreements with the Specialty Pharmacies to restrict cartridges to Remodulin only. (ECF No. 322-1 ¶ 78; ECF No. 336-1 ¶ 78.) In late 2018, Smiths emailed a Specialty Pharmacy distributor, requesting it sign the amended agreement "that requires us to only sell [CADD-]MS3 cartridges to UTC designated customers,"

adding, "[t]his is not a lot of dollars, but is very important to UTC to prevent generic drug users, and to manage a tight supply chain." (ECF No. 320-1 ¶ 32; ECF No. 362-1 ¶ 32.) However, in December 2018, UTC learned Smiths's agreements with the Specialty Pharmacies limiting cartridges for Remodulin only were never executed. (ECF No. 322-1 ¶ 81; ECF No. 336-1 ¶ 81.) UTC also learned at the time that Sandoz was preparing to launch its generic treprostinil. (*Id.*) UTC repeated its request for Smiths to execute agreements with the Specialty Pharmacies to restrict sale of the cartridges to Remodulin only. (ECF No. 320-1 ¶ 33; ECF No. 362-1 ¶ 33.)

Faced with the prospect the cartridges could be siphoned for other uses, including sudden large purchases, because the Specialty Pharmacies had yet to execute amended agreements with Smiths, UTC requested Smiths place the cartridges "on allocation." (ECF No. 322-1 ¶ 82; ECF No. 336-1 ¶ 82; ECF No. 320-1 ¶ 35; ECF No. 362-1 ¶ 35.) As a result, Smiths agreed UTC could approve every cartridge sale by Smiths to the Specialty Pharmacies until they agreed to limit cartridge sale to Remodulin patients only. (ECF No. 322-1 ¶ 82; ECF No. 336-1 ¶ 82.)

4. 2019 Amended Supply Agreement

UTC requested the cartridges remain on allocation until restrictions were put on the Specialty Pharmacies to limit cartridge use. (ECF No. 320-1 ¶ 37; ECF No. 362-1 ¶ 37.) While on allocation, UTC would approve the release of cartridges, provided that it received confirmation the cartridges were only going to Remodulin patients. (ECF No. 320-1 ¶ 39; ECF No. 362-1 ¶ 39.) By March 2019, the Specialty Pharmacies agreed to sign the amended agreements with Smiths to restrict use of the cartridges to Remodulin only.[5] (ECF No. 320-1 ¶¶ 49–50; ECF No. 362-1 ¶¶ 49–

[5] In February 2019, CVS signed the amended agreement with Smiths, in which CVS "agree[d] to restrict use and/or sale of the Cartridges to patients or customers using the Cartridge in the delivery of [Remodulin] regardless of whether repurchased directly from Smiths [] or indirectly through third parties." (ECF No. 320-1 ¶ 49; ECF No. 362-1 ¶ 49.) In March 2019, Accredo signed its amended agreement with Smiths, in which Accredo "agree[d] that it will only sell and/or use, as

50.) Smiths opted out of counter-signing the agreements with the Specialty Pharmacies. (ECF No. 320-1 ¶ 51; ECF No. 362-1 ¶ 51.) Instead, in April 2019, Smiths entered into a third amended supply agreement with UTC ("2019 Supply Agreement"). (ECF No. 322-1 ¶ 85; ECF No. 336-1 ¶ 85.) Pursuant to the 2019 Supply Agreement, UTC took title to all Smiths's cartridges and became the sole distributor of cartridges compatible with the CADD-MS 3 pump. (ECF No. 320-1 ¶ 54; ECF No. 362-1 ¶ 54.) Thereafter, UTC contracted with the Specialty Pharmacies to reflect that UTC took title to the cartridges and to specify the terms and conditions for purchasing the cartridges from UTC. (ECF No. 322-1 ¶ 86; ECF No. 336-1 ¶ 86.)

5. Sandoz's March 2019 Generic Launch

In August 2018, Sandoz entered into a promotion agreement with RareGen for the marketing of generic treprostinil. (ECF No. 445 § 3, ¶ 18.) In October 2018, RareGen learned from Smiths that UTC had all of Smiths's stock of CADD-MS 3 pumps and UTC had to give permission for any of it to be sold. (ECF No. 322-1 ¶ 139; ECF No. 336-1 ¶ 139.) Notwithstanding, Sandoz and RareGen (collectively, the "Sandoz Parties") were still able to obtain CADD-MS 3 pumps from one of the Specialty Pharmacies. (ECF No. 322-1 ¶ 147; ECF No. 336-1 ¶ 147.) There were more than 3,000 CADD-MS 3 pumps owned by Accredo that were available for generic treprostinil. (*Id.*) According to Sandoz, the availability of CADD-MS 3 pumps was not a limiting factor to its launch. (*Id.*) However, Sandoz was unable to secure the cartridges required for subcutaneous use of its generic treprostinil.

In January 2019, Accredo informed Sandoz the cartridges can only be used with Remodulin. (ECF No. 322-1 ¶ 151; ECF No. 336-1 ¶ 151.) In an effort to obtain cartridges, the

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applicable, the Cartridges for the sole purpose of delivering [UTC]'s Remodulin [] drug to PAH patients, regardless of whether the Cartridges are purchased directly from Smiths [] of [sic] indirectly through third parties." (ECF No. 320-1 ¶ 50; ECF No. 362-1 ¶ 50.)

Sandoz Parties contacted Smiths to discuss potential options. (ECF No. 322-1 ¶¶ 164–65; ECF No. 336-1 ¶¶ 164–65.) During a January 15, 2019 telephone call between the Sandoz Parties and Smiths, Smiths referenced the exclusive arrangement with UTC for the manufacture of cartridges through 2022. (ECF No. 322-1 ¶ 164; ECF No. 336-1 ¶ 164.) However, Smiths suggested the Sandoz Parties "could potentially license" Smiths's "design for the MS-3 cartridge so that [the Sandoz Parties] could go and make it on [their] own." (ECF No. 322-1 ¶ 165; ECF No. 336-1 ¶ 165.) On March 25, 2019, Sandoz launched generic treprostinil for intravenous administration only, beginning the clock on a statutory 180-day period of exclusivity. (ECF No. 445 § 3, ¶ 19.) On March 26, 2019, Smiths sent Sandoz a proposed licensing agreement with terms Sandoz requested. (ECF No. 322-1 ¶ 169; ECF No. 336-1 ¶ 169.) Sandoz responded with an additional demand, requesting Smiths provide "an interim supply of cartridges for the period during which we are negotiating the license agreement[.]" (ECF No. 322-1 ¶ 170; ECF No. 336-1 ¶ 170.) Unable to accommodate Sandoz's demand, Smiths and Sandoz ended their proposed licensing agreement discussions. (ECF No. 322-1 ¶ 171; ECF No. 336-1 ¶ 171.)

In May 2019, RareGen entered into a Joint Development Agreement with Carelife, a device manufacturer, to produce alternative cartridges. (ECF No. 322-1 ¶ 174; ECF No. 336-1 ¶ 174.) In June 2020, the Sandoz Parties submitted a 510(k) application to the FDA for clearance of its alternative cartridges manufactured by Carelife. (ECF No. 322-1 ¶¶ 181–82; ECF No. 336-1 ¶¶ 181–82; ECF No. 445 § 3, ¶ 22.) However, the FDA rejected the Sandoz Parties' application for an alternative cartridge because Smiths's user manual for its CADD-MS 3 pump provides the CADD-MS 3 pump is only compatible for use with Smiths's medical cartridge.[6] (ECF No. 322-1

[6] The FDA noted that the CADD-MS 3 pump manual states, "Use only Smiths [] 3 ml Medication Cartridges; other manufacturers' products will not work with the CADD-MS 3 Pumps." (ECF No. 322-1 ¶ 183; ECF No. 336-1 ¶ 183.) Therefore, the FDA advised the Sandoz Parties "to either

¶ 183; ECF No. 336-1 ¶ 183.) Smiths thereafter worked with the Sandoz Parties to facilitate FDA clearance of Sandoz's alternative cartridges for use with the CADD-MS 3 pump. (ECF No. 322-1 ¶¶ 184–85; ECF No. 336-1 ¶¶ 184–85.) The FDA cleared the alternative cartridges in March 2021, and Sandoz launched its generic treprostinil in the United States for subcutaneous administration in May 2021. (ECF No. 445 § 3, ¶¶ 23–24.) In total, the Sandoz Parties' efforts to develop an alternative cartridge cost approximately $500,000. (ECF No. 322-1 ¶ 188; ECF No. 336-1 ¶ 188.) Based on the relevant dates described above, the damages period is from April 2019, after Sandoz's intravenous-only launch, to March 2021, the month that the FDA approved an alternative cartridge.

B. Procedural History

On April 16, 2019, the Sandoz Parties[7] filed their Complaint, asserting six claims against UTC and Smiths: (1) restraint of trade under 15 U.S.C. § 1 of the Sherman Antitrust Act (Count One); (2) monopolization under 15 U.S.C. § 2 of the Sherman Antitrust Act (Count Two); (3) restraint of trade under N.J. Stat. Ann § 56:9-3 (Count Three); (4) restraint of trade under N.C. Gen. Stat. § 75-1 (Count Four); (5) unfair trade practices under N.C. Gen. Stat § 75-1.1 (Count Five); and (6) tortious interference with prospective economic advantage (Count Six). (ECF No. 1.)

On May 24, 2019, UTC and Smiths filed a Motion to Dismiss. (ECF No. 53.) On June 17, 2019, the Sandoz Parties filed their opposition to UTC and Smiths's Motion to Dismiss. (ECF No.

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work with Smiths [] to submit a new 510(k) allowing the use of this cartridge with their device or identify a different pump which allows 3rd party cartridges to be used with it." (*Id.*)

[7] At an uncertain juncture, RareGen took an inactive role in this litigation. RareGen's most recent filing was a motion to withdraw counsel dated February 2, 2024, which noted that RareGen was still represented by separate counsel. (ECF No. 455.) It is understood that RareGen merged with Liquidia Technologies ("Liquidia") in 2020 operating under the latter's name. RareGen is still listed as a plaintiff on the docket, but the company and/or its successor entity did not participate at trial.

56.) On June 24, 2019, UTC and Smiths filed a reply in further support of their Motion to Dismiss. (ECF No. 59.) On October 4, 2019, Sandoz moved for a Preliminary Injunction. (ECF No. 106.) On October 25, 2019, UTC filed an opposition to the Preliminary Injunction. (ECF No. 122.) Thereafter, the Court issued an opinion and order denying both the Motion for a Preliminary Injunction and Motion to Dismiss. (ECF Nos. 168, 169.)

On February 12, 2020, UTC and Smiths filed Answers to the Complaint. (ECF Nos. 171, 172.) On March 30, 2020, the Court entered a consent order allowing the Sandoz Parties to file an Amended Complaint. (ECF No. 177.) On the same day, the Sandoz Parties filed their Amended Complaint (ECF No. 178) in which Sandoz asserted a breach of contract claim against UTC arising from its alleged failure to carry out its obligations under the 2015 Settlement Agreement (Count Seven). (*Id.* ¶¶ 107–21).

On April 17, 2020, UTC filed a Motion to Dismiss Count Seven of the Sandoz Parties' Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). (ECF Nos. 179, 181.) On May 11, 2020, the Sandoz Parties filed an opposition to UTC's Motion to Dismiss. (ECF No. 184.) On May 18, 2020, UTC filed a reply in further support of its Motion to Dismiss. (ECF No. 187.) On November 18, 2020, the Court denied UTC's Motion to Dismiss Count Seven of Sandoz's Amended Complaint. (ECF Nos. 251, 252.)

On November 13, 2020, the Sandoz Parties settled with Smiths (ECF No. 246), and all claims against Smiths were dismissed with prejudice (ECF No. 247). Under the settlement, Smiths paid $4.25 million to the Sandoz Parties. (Sandoz's Tr. Ex. ("PX") 95 § 2.a.) It is undisputed that Sandoz received $2.125 million from this settlement.

On December 16, 2020, UTC answered Sandoz's Amended Complaint and asserted a counterclaim for "fraudulent concealment—spoliation" against Sandoz. (ECF No. 258 ¶¶ 72–97.)

On January 6, 2021, Sandoz filed a Motion to Dismiss UTC's Counterclaim pursuant to Federal Rules of Civil Procedure 8 and 9(b). (ECF No. 264; Sandoz's Mot. Br. (ECF No. 265).). On February 2, 2021, UTC filed its opposition to Sandoz's Motion to Dismiss. (ECF No. 273.) On February 9, 2021, Sandoz filed a reply in further support of its Motion to Dismiss. (ECF No. 276.) On August 31, 2021, the Court granted Sandoz's Motion to Dismiss UTC's Counterclaim. (ECF Nos. 315, 316.)

On September 10, 2021, Sandoz filed a Motion for Partial Summary Judgment (ECF No. 319; Sandoz's Mot. Br. (ECF No. 320)), and UTC filed its Motion for Summary Judgment (ECF No. 321; UTC's Mot. Br. (ECF No. 322)). On October 22, 2021, UTC filed its opposition to Sandoz's Motion for Partial Summary Judgment (ECF No. 341),[8] and on November 1, 2021, Sandoz filed its opposition to UTC's Motion for Summary Judgment (ECF No. 348). On December 3, 2021, UTC filed its reply in further support of its Motion for Partial Summary Judgment (ECF No. 365), and Sandoz filed its reply in further support of its Motion for Summary Judgment (ECF No. 364).[9]

On October 20, 2021, UTC filed a Motion to Exclude damages opinions of Dr. Anupam Jena. (ECF No. 333.) On November 1, 2021, the Sandoz Parties filed an opposition (ECF No. 348),

[8] On December 1, 2021, UTC filed an amended brief in opposition to Sandoz's Motion for Partial Summary Judgment, which was accompanied by an amended response to Sandoz's statement of material facts and supplemental statements of disputed material facts. (ECF No. 362.) On February 17, 2022, the Sandoz Parties filed a correction to papers submitted in support of the Sandoz Parties' opposition to UTC's motion for summary judgment, replacing an exhibit that was previously submitted. (ECF Nos. 377, 378.) The Sandoz Parties also filed two corrections to papers submitted in support of Sandoz's reply in support of its motion for partial summary judgment, correcting clerical errors to citations in its brief and supplemental statement of disputed material facts. (ECF Nos. 377, 379.)

[9] The Court refrained from addressing the parties' summary judgment motions to allow the parties an opportunity to resolve the litigation. The parties appeared for mediation before the Honorable Joseph A. Dickson, U.S.M.J. (ret.) but were unsuccessful.

and on November 22, 2021, UTC filed its reply (ECF No. 358).

On March 30, 2022, the Court issued an opinion and order granting Sandoz's Motion for Partial Summary Judgment, granting in part and denying in part UTC's Motion for Summary Judgment, and denying UTC's Motion to Exclude. (ECF Nos. 382, 383.) Sandoz's antitrust claims (Counts One and Two), restraint of trade claims (Counts Three and Four), unfair trade practices claim (Count Five), and tortious interference claim (Count Six) were dismissed with prejudice. (*Id*.) In the March 30, 2022 Opinion, the Court found UTC was liable on Sandoz's breach of contract claim arising under Count Seven. (ECF No. 382.) The Court held that, "[b]y taking efforts to become the 'sole distributor' of cartridges and entering into agreements with the Specialty Pharmacies to restrict cartridge distribution for Remodulin use only, UTC took actions that [breached] the 2015 Settlement Agreement" with Sandoz. (*Id.* at 39–40.) Additionally, the Court found the breach occurred in 2019. (*Id*. at 40 ("To the extent UTC contends it obtained the exclusive cartridge supply in 2016, not 2019, the record indicates otherwise. . . . UTC did not take title to the cartridges and enter into express agreements with the Specialty Pharmacies to restrict cartridge distribution until 2019.").) Following the March 30, 2022 Opinion, Sandoz's damages as to the breach of contract claim was the sole unresolved issue before the Court.

On March 24, 2023, Sandoz filed a Motion to Preclude UTC's Expert from Offering Certain Opinions and Testimony at Trial. (ECF No. 414; Sandoz's Mot. Br. (ECF No. 415)). On April 20, 2023, UTC filed its opposition to Sandoz's Motion to Preclude. (ECF No. 431.) On May 4, 2023, Sandoz filed its reply in further support of its Motion to Preclude. (ECF No. 434.)

On April 13, 2023, UTC and Sandoz each filed Motions *in Limine*. (ECF Nos. 422–28.) On May 11, 2023, Sandoz filed an opposition to UTC's Motions *in Limine* (ECF Nos. 439, 440), and UTC filed an opposition to Sandoz's Motions *in Limine* (ECF Nos. 437, 438). On October 5,

2023, Judge Allen entered the Final Pretrial Order. (ECF No. 445.) On October 17, 2023, the Court issued an opinion and order: (1) granting in part and denying in part Sandoz's Motion to Preclude; (2) granting in part, denying in part, and reserving in part UTC's Motions *in Limine*; and (3) granting in part and reserving in part Sandoz's Motions *in Limine*. (ECF Nos. 447, 448.)

The Court held a three-day bench trial to determine Sandoz's damages on its breach of contract claim. The bench trial began on April 29, 2024 and concluded on May 1, 2024. On the last day of trial, UTC filed an Offer of Proof under Federal Rule of Evidence 103.[10] (ECF No. 485.) Thereafter, on May 24, 2024, the parties submitted proposed findings of fact and conclusions of law under seal.[11] (ECF Nos. 493, 494.) On the same date, the parties also provided a joint trial exhibit list which was filed onto the docket (ECF No. 492),[12] and post-trial deposition designations, counter-designations, and counter-counter designations submitted via email. Closing arguments were held on June 4, 2024.

[10] UTC submitted the Offer of Proof in light of the Court's time and witness limitations as well as the Court's evidentiary rulings prior to and during trial. (ECF No. 485.) The Offer of Proof provides an outline of testimony to which UTC's witnesses—both additional witnesses and witnesses that actually testified—would have testified had they been permitted. (*Id.* at 2–7.) Upon review of the Offer of Proof, the Court determines that its findings reflected in this Opinion would not have been affected by its consideration of this additional testimony. A three-day trial to determine damages on a breach of contract claim was an ample amount of time given the considerations of judicial economy.

[11] On May 28, 2024, the parties filed redacted versions of their proposed findings of fact and conclusions of law. (ECF Nos. 497, 499.)

[12] The joint trial exhibit list includes the parties' evidentiary objections to their adversary's exhibits as the Court reserved decision on many of the objections in order to expedite trial. The objections will be adjudicated to the extent necessary for the purposes of this Opinion.

C. Sandoz's Trial Witnesses[13]

1. Robert Spina[14]

Robert Spina testified on April 29, 2024, and offered testimony relating to the launch of generic treprostinil. Overall, the Court found Mr. Spina to be a credible witness, and accorded his testimony commensurate weight.

Mr. Spina worked at Sandoz from 2015 to 2021, and at the time of his departure was the vice president of marketing, market access, and patient services. (Spina Trial Tr. 41:14–19.) Mr. Spina previously held roles as the vice president of pricing and contracts, vice president of sales and marketing, and vice president of key accounts and sales. (*Id.* 42:9–13.)

Mr. Spina testified about Sandoz's mission and background. (*Id.* 44:1–11.) Mr. Spina testified as to the importance of generic medicines. (*Id.* 45:20–46:5.) Mr. Spina defined the term "payers" as commercial insurance companies that reimburse for the cost of products and services and are incentivized to reduce health care costs by encouraging prescriptions of generics (*Id.* 61:1–2; 61:1–9.) As to treprostinil, Mr. Spina testified that the subcutaneous method of administration is preferred because it allows patients to have greater mobility, and it does not involve a procedure

[13] The Court's credibility determinations for all of the trial witnesses were based, not only on a witness's response to a particular question, but also the witness's physical reaction (*i.e.* body language, facial expressions, furtive movements, shifting, squirming, folding of their arms, *etc.*). *See* Third Circuit Model Civil Jury Instructions § 1.7 (noting a jury should consider several factors in determining the credibility of a witness including "(1) the opportunity and ability of the witness to see or hear or know the things the witness testifies to; (2) the quality of the witness's understanding and memory; (3) the witness's manner while testifying; (4) whether the witness has an interest in the outcome of the case or any motive, bias or prejudice; (5) whether the witness is contradicted by anything the witness said or wrote before trial or by other evidence; (6) how reasonable the witness's testimony is when considered in the light of other evidence that you believe; and (7) any other factors that bear on believability.").

[14] Due to the voluminous nature of the written record of the trial proceedings, the Court references the transcripts as "[Witness Name] Trial Tr."

that could cause a risk of infection. (*Id.* 48:1–5.) Mr. Spina opined that the Specialty Pharmacies were prepared to support Sandoz's launch of generic treprostinil. (*Id.* 55:24–57:9.)

Mr. Spina testified that treprostinil was a complex, generic drug covered as a medical benefit with payers. (*Id.* 50:24–51:6, 65:20–66:6.) Previously, Sandoz had launched complex, injectable medications covered as a medical benefit which have achieved a penetration rate of 75% to 90%. (*Id.* 66:17–70:2.) Based on his experience with other complex launches, Mr. Spina testified that Sandoz believed generic treprostinil would have a generic penetration rate of 50% to 60%.[15] (*Id.* 68:22–69:1.) Mr. Spina testified that Sandoz expected there would be dispense-as-written ("DAW") prescriptions for Remodulin because treprostinil is a complicated product, and there may be physicians reluctant to switch to the generic. (*Id.* 70:15–22.)

Mr. Spina testified that Sandoz partnered with RareGen to ensure a successful treprostinil launch. (*Id.* 50:15–51:6.) When asked whether Sandoz was ready to launch generic treprostinil in March 2019, Mr. Spina testified "we had approval, we had product, we had agreements with the specialty pharmacies. We were very ready." (*Id.* 73:21–22.) Mr. Spina noted that Sandoz considered delaying the launch of generic treprostinil, but Sandoz decided to launch intravenous-only generic treprostinil because of its responsibility as a company to bring affordable medications to patients. (*Id.* 73:25–74:10.) Mr. Spina acknowledged that Sandoz did not foresee that the inability to offer subcutaneous administration would have a large impact on intravenous sales. (*Id.* 75:9–13.) Mr. Spina testified about a failed generic launch by Teva Pharmaceutical Industries Ltd. ("Teva"). (*Id.* 75:20–25.) Teva came to market with a generic called Flolan, an epoprostenol used to treat PAH, but immediately had manufacturing issues and were unable to

[15] Generic penetration rate refers to the rate at which the generic medication would enter the market. For example, here, generic penetration rate is the percentage of all treprostinil sales that would have been comprised of generic treprostinil.

fulfill patient demands for the medication. (*Id.* 76:11–14.) Mr. Spina testified that Sandoz was unable to achieve its forecasted sales due to the restriction of access to cartridges forcing Sandoz to destroy more than $6 million worth of product, which is uncommon and damaging for generic companies because profit margins are thin. (*Id.* 77:2–15.)

On cross-examination, Mr. Spina stated Sandoz decided to offer payer rebates following the cartridge restriction. (*Id.* 121:5–13.) Mr. Spina acknowledged that Sandoz lost its contractual relationship with CVS and was replaced by Teva. (*Id.* 136:17–137:6.) Mr. Spina acknowledged that "marketing" is an expense. (*Id.* 150:20–23.)

2. Scott Moomaw

Scott Moomaw testified on April 29 and April 30, 2024, and offered testimony relating to the forecasting of sales for generic treprostinil. Overall, the Court found Moomaw to be a credible witness, and accorded his testimony commensurate weight.

Mr. Moomaw has been the chief commercial officer at Liquidia since 2020 when RareGen merged with Liquidia. (Moomaw Trial Tr. 159:5–11.) Mr. Moomaw was the chief operating officer at RareGen. (*Id.* 159:13–14.) Prior to RareGen, Mr. Moomaw worked as associate vice president of marketing for about six years at UTC where he worked on Remodulin; Tyvaso, an inhaled form of treprostinil; and Orenitram, an oral form of treprostinil. (*Id.* 160:10–17.)

Mr. Moomaw testified about the founding of RareGen and its founding members. (*Id.* 160:21–164:10.) Mr. Moomaw noted aspects of the business arrangement between the Sandoz Parties, and each party's responsibilities. (*Id.* 164:18–167:13.) Mr. Moomaw testified as to RareGen's approach to marketing generic treprostinil. (*Id.* 167:24–170:20.) RareGen was responsible for developing sales forecasts of generic treprostinil prior to the launch. (*Id.* 170:22–171:5.) Mr. Moomaw was a part of RareGen's forecasting team. (*Id.*) Mr. Moomaw

testified that the development of an accurate forecast is important because a forecast directs a company's production, resourcing, and budgeting. (*Id.* 172:1–19, 183:17–184:2.) An inflated or inaccurate forecast in the pharmaceutical industry can lead to overproduction necessitating the destruction of product, which is what happened to Sandoz's supply of generic treprostinil. (*Id.* 184:3–5.) Mr. Moomaw stated that the April 2019 forecast[16] was important for the Sandoz Parties' preparation in offering a subcutaneous administration of generic treprostinil. (*Id.* 184:18–185:13; *see* PX 64.) Mr. Moomaw acknowledged that he considered Teva's failed launch of Flolan in forecasting Sandoz's market share. (*Id.* 181:3–12.)

Mr. Moomaw testified that the subcutaneous cartridge restriction "dramatically" impacted intravenous sales. (*Id.* 197:5–10.) Mr. Moomaw testified that Humana Inc., "a very, very large payer," originally notified patients that they were going to mandate generic treprostinil, but disavowed this position after learning that Sandoz was unable to provide a subcutaneous route of administration for its generic. (*Id.* 204:11–18.) Prior to launch, Mr. Moomaw was not under the impression that rebates would be necessary to secure payer's support. (*Id.* 202:4–9.) However, following Humana's changed position and other feedback, the Sandoz Parties were forced "to reevaluate the rebate strategy." (*Id.* 205:2–5.) Upon learning that the cartridge restriction forced Accredo to abandon its original strategy of promoting generic treprostinil, the Sandoz Parties realized they "probably needed to go ahead and offer rebate[s]." (*Id.* 206:4–208:8.) Mr. Moomaw testified that the Sandoz Parties were "swimming against the current with the specialty pharmacies because while they had been supportive of the generic prior to launch, they got to the point that

[16] The April 2019 forecast is discussed at length in this opinion. It is one of the many forecasts that RareGen completed to plan for a joint intravenous and subcutaneous launch of treprostinil. This forecast will be referred to hereinafter as the "April 2019 forecast" or "RareGen's April 2019 forecast."

they were requesting the payers directly that they not require the generic. . . . Again, given the issue with the subcutaneous market." (*Id.* 206:4–9.)

On cross-examination, Mr. Moomaw acknowledged that the April 2019 forecast does not indicate "most of the inputs that went into [the] forecast." (*Id.* 229:20–230:17.) Mr. Moomaw was unable to recall any specific inputs that were applied, such as the applied rate at which physicians would prescribe Remodulin instead of generic treprostinil via DAW prescriptions. (*Id.* 229:20–230:17.) When questioned whether that rate would have been written down somewhere in the voluminous discovery, Mr. Moomaw testified that the forecast team "talked most of the time. So it's very possible that you would not have found it written down because we could have communicated it verbally." (*Id.* 230:11–17.) Mr. Moomaw also acknowledged that prior to RareGen's merger with Liquidia, Liquidia hired an investment bank which opined that the April 2019 forecast for generic treprostinil was too "rosy." (*Id.* 236:16–19.) Mr. Moomaw acknowledged that Sandoz does not offer a patient assistance program ("PAP"). (*Id.* 266:13–17.)

On re-direct, Mr. Moomaw testified RareGen offered the same patient services that UTC offered, except a PAP. (*Id.* 277:15–17.) Mr. Moomaw testified that he was "not aware of any generic company that offers a patient assistance program." (*Id.* 277:13–14.) Mr. Moomaw also stated that RareGen's forecasting accounted for delays with fee schedules and the payers. (*Id.* 280:16–18.) Mr. Moomaw clarified that his modeling was not based on Flolan because there were a number of reasons why Flolan did not succeed which were not comparable to Sandoz's generic treprostinil. (*Id.* 279:12–16.) Further, Mr. Moomaw testified that the April 2019 forecast accounted for the potential of DAWs. (*Id.* 280:7–11.)

3. Dr. Anupam Jena

Dr. Anupam Jena, M.D., Ph.D. testified on April 30, 2024, and offered testimony regarding

Sandoz's lost profits damages. Overall, the Court found Dr. Jena to be a credible and reliable witness, and accorded his testimony commensurate weight.

Dr. Jena is an economist, physician, and a professor at Harvard Medical School. (Jena Trial Tr. 283:7–9.) Dr. Jena is a practicing physician at Massachusetts General Hospital where he has treated a handful of patients with PAH and a lot of patients with complex, fragile medical conditions. (*Id.* 284:1–4.) The Court accepted Dr. Jena as an expert in economics and in general medicine. (*Id.* 283:17–18.)

Dr. Jena testified that his assignment was to calculate the profits that the Sandoz Parties lost as a result of UTC's breach of contract. (*Id.* 284:6–9.) Dr. Jena stated that profit-share payments are not amounts that should be deduced when calculating lost profits damages because "[t]hat's just a split of profits," and not "costs that are required to generate sales." (*Id.* 291:5–11.) Dr. Jena noted that economists routinely consider sales forecasts such as launch projections when calculating but-for sales that would have occurred absent a breach. (*Id.* 297:25–298:9.)

Dr. Jena ultimately relied upon the April 2019 forecast which fell in the middle of other forecasts prepared by the Sandoz Parties, *i.e.,* there were some forecasts with higher projections and some forecasts with lower projections. (*Id.* 300:7–21.) Dr. Jena validated the estimates in the April 2019 forecasts by comparing it to various sources. (*Id.* 303:4–312:10, 335:22–336:17.) Dr. Jena further provided testimony as to why he relied upon RareGen's April 2019 forecast. (*Id.* 298:10–299:13.) As a basis for his calculation of damages, Dr. Jena noted that he relied upon sworn deposition testimony which demonstrated that large payers were initially interested in mandating generic treprostinil, but abandoned this position when they learned that Sandoz was unable to offer a subcutaneous administration of generic treprostinil. (*Id.* 324:17–326:15.)

Dr. Jena testified that Flolan was not an appropriate benchmark for generic treprostinil

given the different circumstances. (*Id.* 313:4–18.) Teva lacked PAH expertise, something Sandoz addressed by partnering with RareGen. (*Id.* 313:24–314:4.) Dr. Jena noted that he did consider the impact of COVD-19, and he did not adjust his model because, in a but-for world, Sandoz would have been able to fully launch in March 2019 allowing for most of the generic conversion (55%) to occur before the inception of the COVID-19 Pandemic. (*Id.* 333:23–334:19.)

Dr. Jena testified that the generic penetration rate used in the damages model created by Dr. Sean Nicholson, Ph.D.,[17] was improper because it comes from the real world and does not account for the impact that the cartridge restriction had on the intravenous-only launch. (Jena Trial Tr. 316:4–317:17.) Dr. Jena opines "Dr. Nicholson incorrectly . . . assumes that the inability to launch [subcutaneous], which is 60% percent of patients, had zero impact on [intravenous sales]." (*Id.* 317:15–17.) Dr. Jena testified that Dr. Nicholson's penetration rate used in his model is inconsistent with the academic literature, performance of other complex generic drugs, UTC's own internal projections about Sandoz's generic treprostinil, and market analyst forecasts. (*Id.* 318:1–20.) Dr. Jena submits Dr. Nicholson ignores: "the evidence that payer didn't want to get involved in managing this class once they figured out that [subcutaneous] was not an option for generics"; "the evidence that specialty pharmacies would've had different incentives . . . [in that] they would have been more inclined to steer patients towards generics had the block not occurred"; and "the effect of the reputational harm." (*Id.* 321:11–21.)

On cross-examination, Dr. Jena conceded that he does not "know the number of payers overall who refused to prefer generic treprostinil due to the lack of a subcutaneous option." (Jena Trial Tr. 341:13–18.) Further, Dr. Jena did not "attempt to quantify the number of physicians that

[17] Dr. Nicholson is an economist retained by UTC to review Dr. Jena's damages analysis and identify any methodological errors. (Nicholson Trial Tr. 555:17–21, 593:22–594:1.)

wrote DAWs" pursuant to Accredo's directive compared to physicians who wrote DAWs for other reasons. (Jena Trial Tr. 352:25–353:6.)

D. UTC's Trial Witnesses

1. Kevin Gray

Kevin Gray testified on April 30 and May 1, 2024, and offered testimony regarding the services that UTC provides to PAH patients and physicians. The Court found Mr. Gray to be a credible witness and accorded his testimony commensurate weight.

Mr. Gray worked at UTC for over sixteen years, and, at the time of his retirement, he was a senior vice-president of strategic operations at UTC. (Gray Trial Tr. 399:1–21.) Mr. Gray provided background information about UTC and its inception. (*Id.* 403:16–406:2.) Mr. Gray testified about UTC's workforce and the number of employees that were working within the PAH community. (*Id.* 417:13–423:24.)

On cross-examination, Mr. Gray testified that, during the relevant period, Remodulin was UTC's best-selling drug annually generating more than $500 million in revenue. (*Id.* 456:23–457:7.) Mr. Gray acknowledged that, during a strengths, weaknesses, opportunities, and threats analysis, UTC noted Sandoz's experience successfully launching generic drugs to treat orphan diseases with small and fragile patient populations. (*Id.* 467:12–471:1.)

2. Dr. Paul Forfia

Dr. Paul Forfia, M.D. testified on May 1, 2024, and offered testimony related to PAH physicians' preferences in prescribing treprostinil. The Court generally found Dr. Forfia to be a credible and reliable witness and accorded his testimony commensurate weight.

The Court accepted Dr. Forfia as a medical expert in the treatment of PAH. (Forfia Trial Tr. 476:11–19.) At Temple University Hospital, Dr. Forfia oversees the treatment of over 500 PAH

patients and follows the treatment of 2,000 patients with other types of pulmonary hypertension. (*Id.* 478:4–9.) Dr. Forfia communicates "[a]lmost every day" with the PAH patients and discusses the treatment of PAH patients with PAH specialists "[a]ll the time." (*Id.* 478:10–25.) Dr. Forfia testified that PAH is known as the "hot potato disease" because of how quickly and often doctors refer PAH patients to PAH specialists due to the "complexity" of PAH medications and "widespread level of discomfort and lack of knowledge" as to PAH. (*Id.* 477:16–478:3.)

Dr. Forfia testified that PAH patients who receive Remodulin are "extremely fragile," "in congestive heart failure," and "often either ambulance-transferred or helicoptered into [the hospital]." (*Id.* 479:2–480:13.) Further, Dr. Forfia noted that "any misstep actually can lead to a significant deterioration or death." (*Id.* 480:16–17.) As to PAH patient and physician reluctance to change therapy, Dr. Forfia testified, "You take a patient who is really sick with PAH and you resuscitate them out of right-sided heart failure and they're living a relatively normal life, try to convince the person to change their medication. I wish you luck." (*Id.* 503:25–504:4.) Dr. Forfia testified that PAH physicians were "outraged" and "[t]otally unwilling" to use generic epoprostenol because it "just landed on the market" with "no switch studies, no efficacy data." (*Id.* 499:11–500:3.)

Dr. Forfia testified that a PAH physician would not "view the lack of a [subcutaneous] option as tainting the ability to prescribe it for patients who were eligible for [intravenous] therapy." (*Id.* 510:13–22.) Dr. Forfia noted PAH physicians do not have a preferred mode of infusion of treprostinil for their patients, and the decision varies "patient to patient." (*Id.* 487:15–24.) Dr. Forfia detailed positive and negative aspects of each mode of infusion. (*Id.* 488:5–489:1, 525:13–526:9, 544:7–545:17.) As to payers, Dr. Forfia stated that he would not check a payer's medical policy before deciding whether to prescribe Remodulin subcutaneously

or intravenously. (*Id.* 489:2–4.) As to Specialty Pharmacies, Dr. Forfia testified, "[It]'s absurd. To think that a specialty pharmacy would be calling me and telling me how to prescribe, it's never happened. I've never seen it happen. Our relationship with the [S]pecialty [P]harmacies is different." (*Id.* 492:24–493:9.) Dr. Forfia testified he has continued to prescribe Remodulin to all of his patients "[u]nless a payer mandates generic treprostinil," which has happened only once. (Forfia Trial Tr. 513:10–22.)

On cross-examination, Dr. Forfia acknowledged that there are roughly 800 to 900 PAH prescribers in the United States. (*Id.* 517:4–6.) Dr. Forfia conceded that he did not do any analysis of physician practices and preferences in treating PAH patients. (*Id.* 514:10–19.) Dr. Forfia did not conduct surveys of PAH physicians to determine whether PAH physicians were reluctant about transitioning patients from Remodulin to generic treprostinil. (*Id.* 514:10–22, 515:10–18, 516:14–517:2.) Dr. Forfia acknowledged that since 2016, UTC has made over 332 payments to him totaling $326,705.00 for "[c]onsulting, lecturing, and various forms of education." (*Id.* 537:9–21.) Dr. Forfia was also confronted with a false or misleading statement in his expert report. (*Id.* 538:20–539:9.)

3. Dr. Sean Nicholson

Dr. Nicholson testified on May 1, 2024, and offered testimony in response to Dr. Jena's damages model. The Court found Dr. Nicholson to be a less reliable and credible witness than Dr. Jena and accorded his testimony commensurate weight.

Dr. Nicholson is a healthcare economist who is a professor at Cornell University. (ECF No. 494 at 4.) The Court accepted Dr. Nicholson as an expert in health economics. (Nicholson Trial Tr. 555:17–21.) UTC retained Dr. Nicholson to review Dr. Jena's damages analysis and identify any methodological errors. (*Id.* 593:22–594:1.)

Dr. Nicholson testified that he did not develop his own damages model or challenge most of the variables used in Dr. Jena's damages model. (*Id.* 592:7–593:3.) Dr. Nicholson opined that the but-for generic penetration rate for subcutaneous treprostinil would have been the same as Sandoz's actual generic penetration rate following its intravenous-only launch. (*Id.* 604:6–11.) Further, Dr. Nicholson testified that, for his damages model, he used real-world generic penetration rates and real-world prices in accordance with the principle of "consistent economic pairing." (*Id.* 597:25–598:9.)

On cross-examination, Dr. Nicholson was unable to recall his deposition testimony as to the availability of pumps for generic treprostinil. (*Id.* 589:18–591:6.) Dr. Nicholson acknowledged that his expert report did not opine that profit-share payments from Sandoz to RareGen should have been deducted from the analysis of Sandoz's damages. (*Id.* 601:9–603:18.) Dr. Nicholson conceded that the J-Code issue created operational challenges which made it more difficult for payers to prefer generic treprostinil. (*Id.* 607:7–22.) Dr. Nicholson acknowledged that he did not conduct an analysis on how often generic drugs offer payer rebates. (*Id.* 610:23–611:9.)

Dr. Nicholson testified he did not find persuasive evidence indicating that payers planned to mandate generic treprostinil but refused to do so because Sandoz could not serve subcutaneous patients. (*Id.* 618:10–14.) However, Dr. Nicholson acknowledged reviewing evidence which established that Accredo initially planned to promote generic treprostinil but changed course due to the cartridge restriction. (*Id.* 623:16–628:9.) Dr. Nicholson further acknowledged he cited to a RareGen document in his report which provided that 26% of physicians were waiting to prescribe intravenous until the subcutaneous route of administration was available. (*Id.* 631:9–13.) Dr. Nicholson did not directly answer whether his reliance on the real-world intravenous penetration rate would be wrong if a single doctor did not prescribe intravenous because the subcutaneous was

not available. (*Id.* 632:11–633:12.)

II. FINDINGS OF FACT[18]

The following section constitutes the Court's findings of fact pursuant to Federal Rule of Civil Procedure 52(a). The findings of fact are derived from the parties' exhibits, witnesses' trial testimony, and the deposition designations' testimony.[19]

A. The Parties and the Products

1. UTC is a pharmaceutical company that was founded over thirty years ago with the "sole purpose . . . to discover and develop medicines for treating PAH" after its founder's daughter was diagnosed with PAH. (Gray Trial Tr. 403:16–404:9.)

2. Since its launch, UTC's Remodulin has treated over 15,000 patients in the United States. (*Id.* 405:23–406:2.) Remodulin costs approximately $150,000 per patient for an annual course of therapy. (Jena Trial Tr. 289:8–19.) In 2018, Remodulin was UTC's best-selling drug generating

[18] If any findings of fact are more appropriately categorized as conclusions of law, and *vice versa*, they are adopted as such.

[19] To the extent the Court credits a witness's testimony or an exhibit that a party objected to, the Court overrules that objection. As the undersigned colloquially noted at trial, "this is a bench trial and I am going to be [the] finder of fact, and I will give whatever weight to whatever document or testimony I deem appropriate. . . . [I]t's not like there's a jury sitting there, [in that case,] we [would] have to worry about them misinterpreting it." (Trial Tr. 253:18–22.) *See Suter v. Gen. Acc. Ins. Co. of Am.*, 424 F. Supp. 2d 781, 790 (D.N.J. 2006) ("Courts have also recognized that in the context of a bench trial, evidence should not be excluded under Rule 403 on the grounds that it is unfairly prejudicial, because the Court is capable of assessing the probative value of the article and excluding any arguably improper inferences." (internal quotation marks and citations omitted)). Sandoz also raised many objections to UTC's exhibits under the premise that certain documents were improperly used by UTC at trial without a sponsoring witness. Although a witness should not be cross-examined about the document that he or she does not have "firsthand knowledge of," *Sullivan v. Warminster Twp.*, 461 F. App'x 157,162 (3d Cir. 2012), the Court finds these objections are misplaced. *See Acorda Therapeutics Inc. v. Apotex Inc.*, Civ. A. No. 07-4937, 2011 WL 4074116, at *6 (D.N.J. Sept. 6, 2011) ("The testimony of a witness is not necessary to authenticate a document." (citing Fed. R. Evid. 903)); *TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, Civ. A. No. 11-00774, 2017 WL 952955, at *1 (N.D. Cal. Mar. 12, 2017) ("There is no freestanding 'sponsoring witness' requirement in the Federal Rules of Evidence.").

more than $500 million in revenue. (Gray Trial Tr. 457:2–7.)

3. The FDA label for Remodulin specifies that subcutaneous infusion is the preferred route of administration because intravenous injections and the placement of an indwelling catheter are associated with a higher risk of life-threating bloodstream infections. (Spina Trial Tr. 48:1–5; Jena Trial Tr. 285:16–23; Forfia Trial Tr. 526:18–21.) The current patient population for injected treprostinil is around 3,000 patients. (Jena Trial Tr. 385:22–386:2; Moomaw Trial Tr. 264:13–15.) Roughly 60% of those 3,000 patients receive treprostinil subcutaneously. (Spina Trial Tr. 48:6–8; Jena Trial Tr. 285:13–15; Forfia Trial Tr. 527:1–3.)

4. Treprostinil is distributed by the Specialty Pharmacies. (Spina Trial Tr. 53:24–54:11.) The Specialty Pharmacies provide ancillary services associated with the administration of treprostinil by providing infusion pumps and cartridges. (*Id.* 54:12–15.) Accredo services approximately 80% of the country's treprostinil patient population treprostinil. (Jena Trial Tr. 319:11–12, 327:4–5.)

5. UTC sells three other PAH medications: Orenitram (oral treprostinil), Tyvaso (inhaled treprostinil), and Adcirca (oral tadalafil). (Gray Trial Tr. 404:14–24; Forfia Trial Tr. 529:10–11.)

6. Sandoz's mission is to develop drugs that would increase access to lower cost affordable medicines in order to improve health care outcomes for patients. (Spina Trial Tr. 44:1–4.) Sandoz manufactures steroids, antibiotics, blood pressure medications, oncology medications, autoimmune disease medications, and biosimilar medications. (*Id.* 44:7–11.)

B. Behind the Scenes of Sandoz's Generic Treprostinil Launch

7. The FDA gave Sandoz's generic treprostinil an AP rating.[20] (Moomaw Trial Tr. 169:20–21; ECF No. 445 § 3, ¶ 20.) An AP-rated generic is subject to state-automatic substitution

[20] An AP rating means that the FDA deems the generic medication to be therapeutically equivalent to the branded medication. (ECF No. 445 § 3, ¶ 20.)

laws which permit, and/or in many states, require pharmacies to dispense the less-expensive generic even when the branded drug is prescribed. (Spina Trial Tr. 60:3–7, 67:25–68:3; Jena Trial Tr. 307:22–308:17.)

8. Generic drugs comprise 91% of all prescriptions in the United States and are chemically equivalent alternatives to high-cost branded drugs. (Spina Trial Tr. 45:20–46:5.) Generic drugs have the same efficacy and outcome but are offered at a substantially reduced cost bringing savings to patients and the health care system as a whole. (*Id.*)

9. Treprostinil is considered a "complex" generic drug because distribution is "limited" as the PAH patient population is "delicate" and "very small." (*Id.* 50:24–51:6.) The launch of generic treprostinil was considered to be "atypical" (*id.* 91:17–21) and "unique" (Shah Dep. Tr. 169:20). Sandoz therefore recognized that generic treprostinil would require a "[b]randed launch approach," (UTC's Tr. Ex. ("DX") 65 at 10), involving "significant commercial risk," (DX 58 at 6, 12). Further, Mr. Spina testified: "we weren't sure that we were the best people to sell it," (Spina Trial Tr. 50:5–6); and "when we thought about the asset, did we have all the skills required to launch it successfully? Not necessarily." (*Id.* 50:25–51:2.)

10. However, Sandoz does have extensive experience launching generic medications for orphan diseases that treat severely ill patient populations. (Gray Trial Tr. 467:12–468:6.) For example, Sandoz successfully launched enoxaparin, an injectable medication that is covered as a medical benefit, which eventually achieved a generic penetration of 80% to 90%. (Spina Trial Tr. 66:22–67:24.) Sandoz was also the first company in the United States to launch a biosimilar medication. (*Id.* 44:19–45:4.) Sandoz manufactures and distributes biosimilar medications that treat delicate patient populations. (*Id.* 45:1–19.) In an attachment to an email entitled "Remodulin War Games," UTC executives recognized that one of Sandoz's core strengths as a competitor

could be Sandoz's extensive experience launching generic medications which treat orphan disease with small, severely ill patient populations. (Gray Trial Tr. 467:17–471:1; PX 8; PX 10.)

11. Although Sandoz had experience in launching complex generic drugs, the company sought a partner with experience in the PAH space to ensure a successful treprostinil launch. (Spina Trial Tr. 50:15–51:6; Moomaw Trial Tr. 160:20–25.) The Sandoz Parties agreed to a promotion agreement. (Moomaw Trial Tr. 165:1–10; PX 126.) RareGen was comprised of many former UTC executives who were experts in PAH. (Spina Trial Tr. 51:10–16.)

12. Mr. Moomaw testified that the founders of RareGen "were aware that Sandoz was looking for a partner," and that RareGen was formed specifically for Sandoz's launch of generic treprostinil, but RareGen also wanted to expand to other PAH treatments. (Moomaw Trial Tr. 160:21–161:14.) RareGen invested $20 million in the launch of generic treprostinil and in return, RareGen received a share of Sandoz's profits. (*Id.* 161:16–25.) One of RareGen's founders was Dr. Roger Jeffs. (*Id.* 162:21–163:23.) Mr. Moomaw testified the following about Dr. Jeffs: he had nearly thirty years of experience in PAH; he worked on the clinical development of epoprostenol, which is the first treatment developed for PAH, at Burroughs Wellcome Fund; he then joined UTC where he worked in research and development as well as clinical development on treprostinil; eventually, Dr. Jeffs served in multiple executive positions at UTC including president, chief operating officer, and co-chief executive officer. (*Id.* 163:7–16.) RareGen's sales team also had substantial experience in the PAH space, with six members having previously worked at UTC. (*Id.* 164:4–10.)

13. The Sandoz Parties formed a joint steering committee ("JSC") to oversee the collective actions undertaken by the Sandoz Parties in launching generic treprostinil. (*Id.* 166:14–24; *see also* PX 126 § 3.1.) The JSC had a broad range of supervisory responsibilities. (*Id.* 167:4–13; *see also*

PX 126 § 3.4.) Sandoz's primary responsibility, as the ANDA holder, was to manufacture generic treprostinil (*id.* 164:13–17), whereas RareGen was primarily responsible for commercialization *i.e.*, sales and marketing (*id.* 164:18–22). RareGen took an active approach to marketing generic treprostinil which included directly engaging physicians, specialty pharmacies, and payers. (*Id.* 167:24–168:4.) As the launch approached, the Sandoz Parties met often and talked daily about strategy. (Spina Trial Tr. 52:1–9.)

14. By early 2019, the Sandoz Parties were prepared to launch generic treprostinil. (*Id.* 49:24–50:7, 73:19–24, 76:21–77:1.) Further, the Specialty Pharmacies were ready to support Sandoz's launch. Specifically, the Specialty Pharmacies had enough CADD-MS 3 pumps and supplies to switch PAH patients to Sandoz's generic treprostinil. (Spina Trial Tr. 54:16–57:9; Moomaw Trial Tr. 272:13–17; Jena Trial Tr. 294:7–21, 392:14–393:8.)

15. At launch, RareGen had ten sales representatives that were marketing generic treprostinil, and one part-time medical science liaison. (Moomaw Trial Tr. 168:5–8, 239:7–240:8.) UTC had about 130 full-time employees that were engaging with the PAH community, including seventy sales representatives, more than twenty PAH nurses, and 12 full-time medical science liaisons, who all worked with PAH physicians, the Specialty Pharmacies, payers, and the patients. (Gray Trial Tr. 417:13–423:24.)

16. Despite RareGen's relatively small workforce, RareGen's approach to marketing generic treprostinil included directly engaging physicians, pharmacies, and payers. (Moomaw Trial Tr. 167:24–168:4.) Specifically, RareGen contacted PAH centers whereby RareGen educated physicians regarding the availability of generic treprostinil, discussed the equivalence of the generic to Remodulin, and informed providers about the services available for their staff and patients. (*Id.* 169:3–13.) RareGen's approach to the Specialty Pharmacies involved "a care model

that was very robust" and "included the same pharmacists . . . [and] the same nurses that the brand used." (*Id.* 169:24–170:7.) Additionally, RareGen "paid for the nurses to go out to the [PAH] patients' homes and teach them about the drug, teach them about the disease, teach them about the pump, [and] help them get started the first time." (*Id.* 170:7–10.) As to payers, RareGen worked with them "from the outset . . . to understand sort of how they viewed [generic treprostinil], what their incentives were, what their motivations were, and ultimately how we could get them to mandate the generic." (*Id.* 170:17–20.)

17. A PAP was the only service that the Sandoz Parties did not offer compared to UTC. (Moomaw Trial Tr. 277:12–17.) PAPs are rare for generic companies. (*Id.*) Only about 5% of Remodulin patients were enrolled in UTC's PAP at the time. (Gray Trial Tr. 437:5–9.)

18. Sandoz viewed RareGen as a partner because RareGen had invested $20 million in the launch of treprostinil, and there was a profit-share agreement between the two. (Spina Trial Tr. 52:15–53:6.) Sandoz did not pay RareGen sales commission or fees. (*Id.* 52:23–53:1.) However, under the promotion agreement between the Sandoz Parties, RareGen was an "independent contractor" for Sandoz and the contractual relationship "did not constitute a partnership." (PX 126 § 13.11.) Sandoz had "final decision-making authority (in its sole discretion) with respect to all RareGen activities related to" generic treprostinil. (*Id.* § 4.4.) Sandoz agreed to pay RareGen a percentage of future sales profits—80% of net profits up to $50 million and 50% of net profits thereafter up to $500 million. (*Id.* § 6.3.)

19. RareGen was responsible for developing sales forecasts of generic treprostinil prior to the launch. (Moomaw Trial Tr. 170:22–171:5.) Mr. Moomaw was a part of RareGen's forecasting team. (*Id.*) Mr. Moomaw has developed "many, many forecasts," including when he was at UTC where he developed forecasts for medications such as Remodulin, Propranolol, Tyvaso, and

Orenitram. (*Id.* 171:21–25.) However, Mr. Moomaw had never "created a prelaunch forecast for a generic drug." (*Id.* 233:18–22.) For the pre-launch forecast of generic treprostinil, Mr. Moomaw created a "top-down model," which involved analyzing generic treprostinil's market share of the addressable market of treprostinil. (*Id.* 173:4–13.) This forecast was updated over time based on market research and conversations with physicians, payers, and the Specialty Pharmacies. (*Id.* 182:18–183:15.)

20. The April 2019 forecast projected a slow uptake of generic penetration rate, starting at 5%, growing to 15% at three months, 40% at six months, and peaking at 65% after two years. (*Id.* 177:9–13; *see* PX 64.) The generic penetration rates contained in the April 2019 forecast were based on: RareGen's PAH experience; conversations with physicians, the Specialty Pharmacies, and payers; and input from Sandoz. (Moomaw Trial Tr. 178:1–23.) The April 2019 forecast projected a much more gradual penetration rate compared to retail generic drugs which usually reach a generic penetration rate of 90% within a year. (*Id.* 179:7–24; Jena Trial Tr. 305:14–306:6.)

21. Additionally, the gradual penetration rates forecasted by RareGen took into account: Teva's failed launch (Spina Trial Tr. 76:9–77:1; Moomaw Trial Tr. 180:12–181:13); the potential for physician reluctance to generic treprostinil resulting in DAWs (Moomaw Trial Tr. 179:25–180:11, 280:5–11); the overall complexity of bringing generic treprostinil to market (*id.* 179:25–180:11); the notion that some payers might move more slower than others in managing the class or finalizing fee schedules with the Specialty Pharmacies (*id.* 280:12–19); and that treprostinil would be covered as a medical benefit drug (Spina Trial Tr. 65:20–67:2).

22. The April 2019 forecast did not account for the market penetration achieved by

epoprostenol, the other PAH-infused generic that had come to market.[21] (Moomaw Trial Tr. 233:7–9; deGoa Dep. Tr. 348:20–23.)

23. RareGen used an earlier version of the April 2019 forecast for its "competitive bid" to sell its marketing services to Sandoz in 2018. (Moomaw Trial Tr. 226:1–227:2.) RareGen provided the April 2019 forecast to Liquidia before their merger in 2020. (*Id.* 235:1–2.)

C. Difficulties Encountered After Launching Generic Treprostinil

24. UTC's breach restricted the availability of cartridges for the CADD-MS 3 pump thereby preventing Sandoz from selling generic treprostinil to 60% of the patient population that received treprostinil subcutaneously. (Spina Trial Tr. 49:10–19, 73:9–13; Jena Trial Tr. 284:14–285:12, 317:12–17.)

25. Sandoz's intravenous-only launch was unsuccessful as sales were well below forecasts. (Spina Trial Tr. 212:6–15; Moomaw Trial Tr. 212:6–15.) The cartridge restriction "had a much larger impact [on the intravenous launch] than [Sandoz] expected." (Spina Trial Tr. 75:9–13.) Sandoz's generic penetration rate in the intravenous segment never exceeded 13% during the damages period, and the overall generic penetration rate, which includes Sandoz's generic competitors, never exceeded 20%. (Jena Trial Tr. 338:2–24; Nicholson Trial Tr. 560:7–561:9.)

26. Sandoz's launch of generic treprostinil faced hurdles with each of the main players—PAH physicians, the Specialty Pharmacies, and the payers.

27. Generic treprostinil encountered difficulties in gaining approval of PAH physicians.

a. The lack of a subcutaneous option potentially played a role in Sandoz's inability to obtain the acceptance of PAH physicians. In the attachment to the "Remodulin War

[21] Generic epoprostenol "never achieved a penetration rate above 10 percent." (Nicholson Trial Tr. 568:23–24.)

Games" email, UTC's own market research, prior to Sandoz's launch of generic treprostinil, revealed that 60% of HCPs "are likely to use generic treprostinil" (PX 10 at 6), whereas a contemporaneous exhibit provided by UTC entitled "Treprostinil Injection – Sales and Marketing Update," showed that 26% of physicians were not prescribing generic treprostinil and specified it was because they were "[w]aiting for [subcutaneous]" to be offered (DX 209). Further, the "incomplete launch" caused reputational harm to Sandoz akin to the reputational harm that Teva suffered following their failed launch of Flolan. (Jena Trial Tr. 314:5–18, 333:9–22.)

b. Dr. Forfia testified that PAH Physicians are reluctant to change a PAH patient's therapy once he or she is stable. (Forfia Trial Tr. 503:22–504:6.) Remodulin is the default for infused therapy for the most fragile patients. (*Id.* 492:5–493:12.) Dr. Forfia further testified that the COVID-19 Pandemic complicated the issue and prevented PAH physicians from monitoring patients making it "absurd" to change a PAH patient's therapy. (*Id.* 512:20–513:9.)

c. Dr. Forfia highlighted four factors which explain PAH Physicians' unwillingness to prescribe generic treprostinil following the launch.

i. Sandoz did not conduct a peer-reviewed study showing PAH patients successfully transition to generic treprostinil. (Forfia Trial Tr. 494:7–496:22.) This kind of study is "relatively common" in the PAH space. (*Id.* 497:24–499:1.) PAH physicians prefer to see "efficacy and safety data" about a new generic from "multiple patients" over "a year or two." (*Id.* 494:7–17, 550:21–551:8.) Instead, Sandoz relied upon the FDA's AP

rating. (Moomaw Trial Tr. 169:15–18, 245:21–23.) Dr. Forfia testified that he was not "accustomed to hearing" about AP ratings, and clinicians are not thinking about these kinds of ratings. (Forfia Trial Tr. 495:18–21; *see also* Montagna Dep. Tr. 129:18–130:2.)

ii. Generic treprostinil did not offer an advantage to the patient compared to Remodulin. (Forfia Trial Tr. 502:22–503:21.) It is "very difficult" to convince a PAH patient to change their medication. (*Id.* 503:22–504:6.)

iii. PAH physicians had developed a loyalty to UTC's long history and knowledge in the PAH space. (Forfia Trial Tr. 504:7–505:7.) Physicians wanted to see the Sandoz Parties provide similar commitments and services that UTC provided. (*Id.*) For instance, UTC provides free medication through its PAP. (*Id.* 505:17–21; Gray Trial Tr. 408:11–409:4.) In contrast, the Sandoz Parties were relatively unknown in the PAH space. (*Id.* 506:7–11.)

iv. PAH physicians considered whether a generic drug provided cost savings "to the individual patient." (Forfia Trial Tr. 509:16–510:12.) It is undisputed that PAH patients "pay very little out of pocket for either" Remodulin or generic treprostinil. (Moomaw Trial Tr. 265:21–23.)

28. The Specialty Pharmacies' actions also impacted Sandoz's launch of generic treprostinil.

a. Although Sandoz expected initial DAWs for generic treprostinil (Spina Trial Tr. 70:15–22, 180:6–11; Moomaw Trial Tr. 279:17–280:11), the actual percentage of DAWs was 83% which far surpasses the 2.5% rate that is observed for a typical generic launch. (Jena Trial Tr. 328:19–329:7.)

b. Accredo developed plans for how to maneuver DAWs and generic treprostinil. Sandoz contends that before UTC's breach and the cartridge restriction, internal Accredo emails described plans for Accredo to contact physicians and encourage them to write prescriptions with DAW notes indicating no physician preference and allowing the pharmacy to prescribe generic treprostinil. (Jena Trial Tr. 319:10–23, 327:21–328:18; Nicholson Trial Tr. 623:16–23.) UTC points to Accredo's actions in 2018 including the establishment of a procedure whereby Accredo would confirm with each PAH physician whether they had a preference for Remodulin or generic treprostinil. (PX 27; DX 393 at 6–7.)[22] The "leading" reason for the actions in 2018 was "sensitivities of generics with PAH patients." (Jena Trial Tr. 348:10–349:18; Tandon Dep. Tr. 210:8–211:7.) Dr. Jena testified that Accredo eventually began telling PAH physicians to write DAWs for Remodulin following the

[22] DX 393, an internal Accredo document from 2018, contains the following about Accredo's messaging to PAH physicians: "consider writing prescriptions for your patients that allow substitutions, which will enable Accredo to dispense the available generic equivalent if it presents savings under your patient's plan." (DX 393 at 6.) Sandoz objects to the Court's consideration of DX 393 as it was not presented at trial. (Joint Trial Exhibit List, App. A (ECF No. 492 at 94–95).) The Court will not consider DX 393 in its determination of the factual findings. *Sivolella v. AXA Equitable Life Ins. Co.*, Civ. A. No. 11-4194, 2016 WL 4487857, at *71 (D.N.J. Aug. 25, 2016) ("A party cannot cure flaws or inaccuracies in its trial presentation through post-trial submissions by simply submitting new [evidence]."). Regardless, the Court is not persuaded by either party's narrative of the facts as it pertains to the restriction of cartridges, Accredo's subsequent actions as to DAWs, and the effect on Sandoz's sales of generic treprostinil. The testamentary evidence does not establish a precise timeline for the development of Accredo's procedures relative to the restriction of cartridges. (*See* Jena Trial Tr. 319:10–23, 327:21–328:18; Nicholson Trial Tr. 623:16–23.) A January 2, 2019 Accredo email (PX 27), which Sandoz places reliance on, states that Accredo's change of course took place in 2018, potentially prior to the understanding that there would be a cartridge restriction. (PX 27 at 1 ("We talked about this before the new year. . . . REMINDER on Remodulin RXs: We are NOT actively making requests for generic prescriptions for Remodulin.") (emphasis in original)).

cartridge restriction due to a variety of reasons including state substitution laws.[23] (Jena Trial Tr. 319:10–23, 327:21–328:18.) However, Dr. Forfia testified convincingly that the Specialty Pharmacies have never asked or required him to prescribe Remodulin instead of generic treprostinil. (Forfia Trial Tr. 492:24–493:9.)

c. Sandoz did not present evidence that CVS pressured PAH physicians to prescribe Remodulin. (Spina Trial Tr. 148:4–15.) Instead, Sandoz recorded that "CVS stated very clearly that they have no conversion guarantees" because "this is a very sensitive patient population of prescribers and patients." (DX 179 at 1.) CVS required sign-off by both "Doctor and Patient" before a switch as "this disease state was different and [therefore] normal switch[es] could not happen." (*Id.*) At the end of 2019, Sandoz lost its contract with CVS to Teva; as a result, Sandoz lost access to fifty patients who were served by CVS. (Spina Trial Tr. 136:14–22, 137:19–25; Moomaw Trial Tr. 269:13–19.)

29. Finally, Sandoz encountered obstacles with the payers.

a. Payers cover approximately 40% of infused treprostinil patients. (Gray Trial Tr. 436:9–18; DX 58 at 5.) Payers are incentivized to reduce healthcare costs; therefore, payers often prefer lower cost generic medications over more expensive branded medications. (Spina Trial Tr. 60:25–61:9; Jena Trial Tr. 304:22–24, 319:6–9.) Sandoz sold its generic treprostinil to the Specialty Pharmacies at an average discount of 32% compared to Remodulin. (Spina Trial Tr. 61:5–62:13; Jena

[23] The Court notes Sandoz did not present evidence regarding the number of states that had laws which mandate generic substitution with or without patient consent. (Spina Trial Tr. 143:6–23.)

Trial Tr. 289:8–19; Nicholson Trial Tr. 605:23–606:2.)

b. Before the launch of generic treprostinil, Sandoz described securing the approval of payers as a "[m]ajor obstacle[]." (DX 62 at 21; *see also* DX 58 at 83 ("[P]ayer mandate approach is high risk.").)

c. At trial, the parties discussed challenges that Sandoz faced in its attempt to gain payer support for generic treprostinil. These challenges primarily fall into two categories: (a) coverage and reimbursement; and (b) preferences and mandates.

d. Coverage and Reimbursement:

i. Remodulin and generic treprostinil are generally covered under a medical benefit. (Spina Trial Tr. 65:20–21; DX 58 at 82.) It is more time consuming to establish coverage under a medical benefit because a payer must update its medical policy which often entails a safety and efficacy review as well as consultations with physicians. (Spina Trial Tr. 102:17–19, 103:6–16, 104:4–7.)

ii. Negotiations between the Specialty Pharmacies and payers can be prolonged. (DX 65 at 19.) Sandoz did not anticipate that Accredo would be slow to update fee schedules with payers. (Spina Trial Tr. 136:10–13.) Following the launch of generic treprostinil, Sandoz identified the "main Payer issue" as "speed & lack of alignment of Payer Fee Schedules between Accredo and Payers." (DX 191 at 1; DX 200 at 1.)

iii. Payers use a "J-Code" to reimburse for medical-benefit drugs. (Spina Trial Tr. 110:6–15.) Remodulin and generic treprostinil share a J-Code. (*Id.*; Moomaw Trial Tr. 249:5–9; Jena Trial Tr. 342:11–20.) Before payers could

reimburse for Sandoz's generic, they had to perform "administrative work" to update their reimbursement systems. (Spina Trial Tr. 78:15–18.) This is not a unique issue as many injectable generics share the same J-Code. (Jena Trial Tr. 342:11–20.) However, payers were slow to perform this administrative work which Sandoz noted was "holding our conversion back." (DX 173.)

iv. Two months following the launch of generic treprostinil, Sandoz estimated the coverage issues described above contributed up to half of lost sales. (DX 182.)

e. Preferences and Mandates:

i. "Preferring a product and mandating it are different." (Spina Trial Tr. 128:1–12.) A payer's mandate of a generic constitutes "forcing" selection of the generic. (*Id.*) When a payer merely prefers the generic, it "create[s] incentives to drive use of" the generic, but doctors remain free to "do what they want." (*Id.* 128:4–6, 129:10–11.)

ii. Payers endorse generics regardless of whether they are covered as a pharmacy or medical benefit, but use different procedures to prefer or mandate generics based on the type of coverage. (Spina Trial Tr. 66:1–16; Jena Trial Tr. 323:9–20.)

iii. Payers were reluctant to mandate or even prefer generic treprostinil. Payers were concerned about the safety of fragile PAH patients and expressed misgivings about "the exact equivalence" of the generic. (DX 220 at 1.) Sandoz recognized "payers have always been a little hesitant to manage

drugs in this class due to the severity of the disease." (*Id.*)

iv. Given the shared J-Code, Sandoz's inability to offer a subcutaneous route of administration may have been detrimental. Treprostinil is sold in the same vial regardless of how it is administered, meaning that payers were unable to utilize the J-Code to distinguish and denote their mandate or preference between intravenous and subcutaneous routes of administration. (Spina Trial Tr. 200:15–24; Moomaw Trial Tr. 278:15–21; Jena Trial Tr. 342:11–20; Nicholson Trial Tr. 607:4–6.) The lack of a distinction between the intravenous and subcutaneous routes of administration made it burdensome for payers to manage the class and resulted in some payers demonstrating an unwillingness to mandate or prefer generic treprostinil. (Spina Trial Tr. 78:25–79:21; Moomaw Trial Tr. 199:16–200:10, 208:10–209:24; PX 72.)

v. Dr. Jena also testified there is documentary evidence suggesting that specific payers were interested in mandating generic treprostinil but did not mandate generic treprostinil because Sandoz was unable to offer a subcutaneous route of administration. (Jena Trial Tr. 325:5–326:7.)

vi. Considering that PAH is a "serious disease state with potential end of life ramifications" in a small patient population, PAH is "a less attractive savings opportunity" for payers and limits payers' incentive to manage the infused treprostinil class. (DX 58 at 6; DX 66 at 1.) There are inherent costs for a payer to implement controls in establishing a preference; therefore, payers "won't do so unless there is value." (PX 130 at 1.) Payers had "no

clear [financial] benefit to preferring the" generic. (DX 157.)

vii. Sandoz did not initially plan to offer rebates to payers. (Spina Trial Tr. 62:14–22; Moomaw Trial Tr. 200:25–201:2.) Companies that produce generic medications rarely offer rebates, and instead gain payer support simply by offering the medication at a substantial discount. (Spina Trial Tr. 61:10–19, 142:16–25; Nicholson Trial Tr. 606:3–24.) Prior to Sandoz's awareness of the cartridge restriction, Sandoz recognized that it may need to offer an optimal rebate strategy. (DX 66 at 2; DX 62 at 34–35.) Instead of rebating payers, Sandoz opted for a strategy that involved providing financial incentives to Accredo. (DX 66 at 1.) Sandoz foresaw rebates as having the potential to be "disastrous" to the profit margin "given the discount stacking." (DX 128 at 2.) Following the difficulties with payers, Sandoz then decided to offer rebates for generic treprostinil. (Moomaw Trial Tr. 205:2–15.) If cartridges were not restricted, it is possible that it would not have been necessary for Sandoz to offer rebates. (Spina Trial Tr. 63:13–18, 65:3–5.) By late 2020, Sandoz had entered three rebate agreements, and soon thereafter Sandoz had six rebate agreements in total. (DX 302 at 3, 5; Moomaw Trial Tr. 270:7–12.)

D. Dr. Jena and Dr. Nicholson's Calculations of Sandoz's Lost Profits

30. Dr. Jena's overall conclusion from his primary damages model was that Sandoz's lost profits are calculated to be $168,449,601.00 with 70% ($117,812,888.00) from lost subcutaneous profits and 30% ($50,636,713.00) from lost intravenous profits. (Jena Trial Tr. 284:20–24; DX 376.) Dr. Jena calculated lost profits by comparing Sandoz's actual profits with the profits that

Sandoz "would have earned [in a but-for world] had the breach of contract not occurred." (*Id.* 286:5–23, 287:16–22.) To calculate Sandoz's but-for profits, Dr. Jena used a formula with three variables: (i) quantity, (ii) price, and (iii) margin. (*Id.* 288:4–18.)

31. Dr. Jena applied the real-world price of generic treprostinil in his primary damages model. (*Id.* 289:2–4.) Dr. Jena's margin variable is calculated by subtracting costs from revenue. (*Id.* 290:13–22.)

32. The quantity variable is calculated, in part, by applying the generic penetration rate. (*Id.* 292:24–293:3.) Dr. Jena reviewed the forecasts created by RareGen over the years and ultimately selected the April 2019 forecast—completed shortly after Sandoz's launch—to help form the basis for his damages model. (*Id.* 296:19–312:10.) Dr. Jena's opinion as to the generic penetration rate mirrored the April 2019 forecast: starting at 5%, 15% after three months, 40% after six months, and then 65% after two years. (*Id.* 293:13–294:1.)

33. Dr. Jena also offers alternative damages models with distinct calculations of damages. (*Id.* 363:19–370:19.) One alternative damages model discussed at trial incorporates the entry of other generic treprostinil medications and calculates damages of $137,226,191.00. (*Id.* 368:21–369:8.) A third damages model discussed at trial calculates total damages to be $94,817,099.00 by accounting for the entry of other generic treprostinil medications and utilizing estimated generic prices from RareGen's April 2019 forecast. (*Id.* 369:17–370:19.)

34. Dr. Nicholson calculates lost profits damages of $38.4 million, assigning zero damages to intravenous sales based on his assumption that the cartridge restriction did not have an impact on Sandoz's intravenous launch. (Nicholson Trial Tr. 604:20–605:3.) Dr. Nicholson does not challenge Dr. Jena's formula for calculating damages. (*Id.* 596:17–20.) Dr. Nicholson utilizes the

same price and margin variables based off of real-world data that Dr. Jena uses.[24] (*Id.* 600:4–17, 601:9–12.) Dr. Nicholson's damages model only differs by not utilizing the same quantity variable—generic penetration rate—as Dr. Jena; specifically, Dr. Nicholson utilized the real-world generic penetration rate that Sandoz achieved in its intravenous-only launch for his damages model. (*Id.* 593:5–9, 601:11–12, 604:6–11.)

35. During the damages period, Sandoz's generic penetration rate for intravenous treprostinil in the real world never exceeded 13%, and the overall generic penetration rate, including Sandoz's generic competition, for intravenous treprostinil did not exceed 20%. (Jena Trial Tr. 338:2–24; Nicholson Trial Tr. 560:7–561:9.)

36. A pivotal difference between Dr. Jena and Dr. Nicholson's calculations is each expert's interpretation of whether there would be a "halo effect."[25] Dr. Jena's damages model incorporates the halo effect in determining generic treprostinil's penetration rate in a but-for world. Essentially, Dr. Jena opines that the halo effect caused a difference between the actual generic penetration rate via Sandoz's intravenous-only launch and the but-for generic penetration rate if Sandoz had been able to launch generic treprostinil subcutaneously and intravenously. On the contrary, Dr. Nicholson's damages model applies the actual generic penetration rate of Sandoz's intravenous-only launch, and as mentioned above, does not assign damages to intravenous sales.

[24] *See id.* 598:3–9 ("[W]hen I use a real-world generic penetration rate to correct Dr. Jena's model it's appropriate for me to use the real-world price that's underlying that profit margin. So that's a consistent economic pairing of real-world price with real-world generic penetration rate.").

[25] UTC refers to the impact the lack of a subcutaneous option due to the cartridge restriction had on Sandoz's real-world sales of intravenous treprostinil as a "halo effect" based on Dr. Jena's choice of words at his pretrial deposition. (*Id.* 339:9–16.)

III. CONCLUSIONS OF LAW

"Claims for lost profits damages are governed by the standard of reasonable certainty." *Schwartz v. Menas*, 279 A.3d 436, 438 (N.J. 2022);[26] *see also Above & Beyond - Bus. Tools & Servs. for Entrepreneurs, Inc. v. Trumbo*, Civ A. No. 21-3042, 2023 WL 7166727, at *6 (D.N.J. Oct. 31, 2023) ("Loss of profits, where based on sound fact and not on mere opinion evidence without factual support, is recognized as a proper measure of damages if 'capable of being estimated with a reasonable degree of certainty.'" (quoting *Stanley Co. of Am. v. Hercules Powder Co.*, 108 A.2d 616, 626 (N.J. 1954)). Notably, "[a]nticipated profits that are remote, uncertain or speculative, however, are not recoverable." *Passaic Valley Sewerage Comm'rs v. St. Paul Fire & Marine Ins. Co.*, 21 A.3d 1151, 1158 (N.J. 2011) (quoting *Perth Amboy Iron Works, Inc. v. Am. Home Assurance Co.*, 543 A.2d 1020, 1033 (N.J. Super. Ct. App. Div. 1988)).

Under the standard of reasonable certainty, "[p]roof of damages need not be done with exactitude." *Totaro, Duffy, Cannova & Co., L.L.C. v. Lane, Middleton & Co., L.L.C.*, 921 A.2d 1100, 1108 (N.J. 2007) (quoting *Lane v. Oil Delivery Inc.*, 524 A.2d 405, 409 (N.J. Super. Ct. App. Div. 1987). Instead, it is sufficient for the plaintiff to "prove damages with such certainty as the nature of the case may permit, laying a foundation which will enable the trier of the facts to make a fair and reasonable estimate." *Id.* (quoting *Lane*, 524 A.2d at 409); *see also Bonjorno v.*

[26] In *Schwartz*, the Supreme Court of New Jersey clarified New Jersey's interpretation of the "new business rule" and "reject[ed] a per se rule barring any new business's claim for lost profits damages, and decline[d] to follow the new business rule." 279 A.3d at 447. The *Schwartz* court further held "[w]e do not view a new business to be in the same position as an established business with respect to such damages, however. . . . [W]e recognize that it is substantially more difficult for a new business than for an experienced business to prove lost damages with reasonable certainty." *Id.* at 447–48 (citations omitted). To the extent UTC intimates that the new business rule is implicated here, the Court finds that assertion is contradicted by the testimony presented at trial which provided that Sandoz is an experienced manufacturer and distributor of complex, injectable medications covered as a medical benefit albeit perhaps not to the full magnitude of the complexity of generic treprostinil.

Kaiser Aluminum & Chem. Corp., 752 F.2d 802, 812 (3d Cir. 1984) ("In constructing a hypothetical world free of the defendants' exclusionary activities, the plaintiffs are given some latitude in calculating damages, so long as their theory is not wholly speculative." (citations omitted)). It is the plaintiff's burden "to prove, by a preponderance of the evidence, that the losses it sought to recover were 'a reasonably certain consequence of the breach.'" *Id.* (quoting *Donovan v. Bachstadt*, 453 A.2d 160, 166 (N.J. 1982)). To satisfy this burden, the plaintiff is required to make "two separate" showings. *Id.* at 1108–09. First, the party must establish the alleged damages were a 'natural and probable consequence'" of the breach. *Id.* at 1109 (quoting *Pickett v. Lloyd's*, 621 A.2d 445, 454 (N.J. 1993)). Second, the party is required "to demonstrate the appropriate method for quantifying that loss." *Totaro*, 921 A.2d at 1109.

A. Sandoz's Lost Profits Were a Natural and Probable Consequence

The Court finds Sandoz's lost profits following the launch of generic treprostinil were a natural and probable consequence of UTC's breach of its promise under the 2015 Settlement Agreement "[n]ot to take any action directly or indirectly to prevent, delay, limit, or otherwise restrict the launch, manufacture, use, sale, offer for sale, importation or distribution of the Sandoz ANDA Product in [the United States]." (ECF No. 320-1 ¶ 11; ECF No. 362-1 ¶ 11.) *See Vibra-Tech Eng'rs, Inc. v. Kavalek*, 849 F. Supp. 2d 462, 497 (D.N.J 2012) ("In the context of a breach of contract action in New Jersey, it has long been established that a party who breaches a contract is liable for all of the natural and probable consequences of the breach of that contract, including lost profits." (internal quotation marks and citations omitted) (collecting cases)).[27]

[27] In its proposed conclusions of law, UTC presents the nuanced conclusion that the parties did not contemplate "at the time of contracting in 2015, that a probable result of delaying Sandoz's access to [subcutaneous] cartridges would be lost [intravenous] sales"; therefore, "Sandoz failed to satisfy its burden of proving [halo effect damages] 'would reasonably be supposed to have been in the contemplation of both parties at the time they made the contract as the probable result of the breach

B. Analysis of the Appropriate Method for Quantifying Damages

One significant dispute for the Court to resolve at trial was the propriety of the generic penetration rates offered by the damages experts—Dr. Jena and Dr. Nicholson. As discussed above, Dr. Jena relied upon RareGen's April 2019 forecast in determining the generic penetration rate, whereas Dr. Nicholson utilized the real-world generic penetration rate that Sandoz achieved in its intravenous-only launch.

1. The Court Adopts Dr. Jena's Generic Penetration Rate

The Third Circuit has expressed "serious reservations about the validity of expert testimony based on prior predictions of sales for a given period when actual performance data for that same time span are available." *Advent Sys. Ltd. v. Unisys Corp.*, 925 F.2d 670, 682 (3d Cir. 1991); *see also Tunis Bros. Co., Inc. v. Ford Motor Co.*, 952 F.2d 715, 739 (3d Cir. 1991) (cautioning that "a growth percentage rate determined only by the plaintiffs' speculation . . . requires the jury to speculate and thus cannot support a compensatory damage award"). The *Advent Sys.* court explained:

> In *Olympia Equipment Leasing Co. v. Western Union Telegraph Co.*, 797 F.2d 370, 382 (7th Cir.1986), *cert. denied*, 480 U.S. 934, 107 S. Ct. 1574, 94 L. Ed. 2d 765 (1987), the Court referred to the "old problem of expert witnesses" and criticized testimony on prospective lost profits. The Court observed that, "[t]he expert in

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of it.'" (ECF No. 494 at 40 (quoting *RNC Sys., Inc. v. Mod. Tech. Grp., Inc.*, 861 F. Supp. 2d 436, 456 (D.N.J. 2012)). Although there was testimony presented at trial providing that it was not foreseeable prior to the launch that the cartridge restriction would result in decreased intravenous sales (*see, e.g.*, Spina Trial Tr: 75:9–13), the Court is not persuaded by UTC's proffered conclusion. The goal of compensatory damages in a breach of contract claim is "to put the injured party in as good a position as . . . if performance had been rendered." *Totaro*, 921 A.2d at 1108 (quoting *Donovan*, 453 A.2d at 165) (alteration in original). Considering this goal, the Court does not find it proper to engage in *ad hoc* reasoning to question whether a subset of Sandoz's lost profits were contemplated by the parties at the time of UTC's breach. Further, recent case law from New Jersey does not apply or mention a foreseeability test—*i.e.*, an analysis of whether the parties contemplated the damages at the time of contracting—as UTC intimates. *Compare Totaro*, 921 A.2d at 1108–09, *with Tousley v. Atl. City Ambassador Hotel Corp.*, 50 A.2d 472, 474 (N.J. 1947).

> this case dazzled the jury with 'an array of figures conveying a delusive impression of exactness'—delusive because the figures had no relation to reality.

925 F.2d at 682. Notwithstanding, the Third Circuit has also provided that, "[i]n some circumstances, an expert might be able to rely on the estimates of others in constructing a hypothetical reality, but to do so, the expert must explain why he relied on such estimates and must demonstrate why he believed the estimates were reliable." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 292 (3d Cir. 2012) (citations omitted). Further, "[b]usinesses are generally well-informed about the industries in which they operate, and have incentives to develop accurate projections. As such, experts frequently use a plaintiff's business plan to estimate the plaintiff's expected profits in the absence of the defendant's misconduct." *Id.* (citation omitted); *see also* N.J. R. Evid. 703 ("The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the proceeding. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence."). The *ZF Meritor* court also noted that "there is no *per se* rule of inclusion where an expert relies on a business plan; district courts must perform a case-by-case inquiry to determine whether the expert's reliance on the business plan in a given case is reasonable." 696 F.3d at 292 (citing *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999) (emphasis omitted)).

Here, the Court finds that Dr. Jena's reliance on the April 2019 forecast to determine the generic penetration rate for his damages model was reasonable. Dr. Jena's credible testimony guides the Court. Dr. Jena validated the estimates in the April 2019 forecasts by comparing it to academic literature, other complex injectable medications, UTC's internal business documents, and market analyst projections. (Jena Trial Tr. 303:4–312:10, 335:22–336:17.) Additionally, Dr.

Jena articulated the reasons why he relied upon RareGen's April 2019 forecast, including that the forecast: (i) was created by individuals with specialized knowledge about PAH; (ii) was used for strategic planning by RareGen which created an incentive for RareGen to use realistic estimates; (iii) contained a robust level of detail; (iv) was updated closest in time to the launch; and (v) looked at a number of different data points. (*Id.* 298:10–299:13.) Dr. Jena also appropriately considered the range of forecasts prepared by RareGen and Sandoz and ultimately relied on the forecast prepared closest in time to Sandoz's launch of generic treprostinil, which incorporates the most up-to-date information available from when Sandoz entered the market. (*Id.* 299:4–17, 300:7–21.)

The Court notes the April 2019 forecast projects a slow and gradual increase in generic penetration rate thereby reasonably estimating minimal generic penetration in the first three months, accounting for the possibility of initial physician reluctance and the possibility that payers would not immediately implement mechanisms to mandate or prefer generic treprostinil. (*Id.* 391:11–22; *see also* Moomaw Trial Tr. 179:25–180:11, 280:5–19.) Further, the Court finds that the April 2019 forecast was a reasonable projection because it is consistent with: (1) UTC's own internal projections that 60% of physicians would prescribe the generic; and (2) market analyst projections that generic penetration would be 50 to 90%. (Jena Trial Tr. 303:4–312:10.) Although retail generic drugs usually reach a generic penetration rate of 90% within a year, the April 2019 forecast reasonably accounted for the complexities of a generic treprostinil and projected a much more gradual penetration rate. (Moomaw Trial Tr. 179:7–24; Jena Trial Tr. 305:14–306:6.) Finally, the gradual penetration rates forecasted by RareGen reasonably and properly accounted for: Teva's failed launch (Spina Trial Tr. 76:9–77:1; Moomaw Trial Tr. 180:12–181:13); the notion that some payers might move slower than others in managing the class or finalizing fee schedules with the Specialty Pharmacies (*id.* 280:12–19); and treprostinil's coverage as a medical

benefit drug (Spina Trial Tr. 65:20–67:2).

Additionally, the Court finds that Dr. Jena's reliance on the April 2019 forecast's generic penetration rate as opposed to generic treprostinil's actual performance data was reasonable in light of the record evidence which establishes the halo effect that Sandoz's inability to offer a subcutaneous option of generic treprostinil had on Sandoz's intravenous-only generic treprostinil launch. *Cf. Altana Pharma AG v. Teva Pharms. USA, Inc.*, Civ. A. No. 04-2355, 2013 WL 12157835, at *5 (D.N.J. May 14, 2013) (finding, in the context of a motion to exclude an expert's opinion in a patent infringement case, that assumptions made by an expert in calculating reasonable royalties, which the opposing party argued disregarded how "events actually unfolded," and, instead, included a hypothetical favorable to the expert's party assessing how the parties might have negotiated prior to infringement, was not "so divorced from the facts of this case as to warrant exclu[sion]"). It is reasonably certain that Sandoz's inability to offer a subcutaneous option of generic treprostinil due to the cartridge restriction had a halo effect on Sandoz's intravenous-only generic treprostinil launch. Specifically, it is reasonably certain that the lack of a subcutaneous option of generic treprostinil influenced PAH physicians and the payers.[28] Dr. Nicholson's claim that Sandoz's generic penetration rate would have been equivalent to the generic penetration rate that Sandoz achieved with its intravenous-only launch is contradicted by the evidence presented at trial.[29]

[28] The Court finds that the testimony and evidence presented at trial merely establishes the speculative nature of the effect that the lack of a subcutaneous option had on the Specialty Pharmacies. (*See* Findings of Fact ¶ 28; *see also* Jena Trial Tr. 352:25–353:6.)

[29] The Court was troubled by Dr. Nicholson's refusal to directly answer whether his reliance on the real-world-intravenous generic penetration rate would be wrong if a single doctor did not prescribe intravenous generic treprostinil because the subcutaneous generic treprostinil was not available. (Nicholson Trial Tr. 632:11–633:12.) Additionally, the Court found Dr. Jena's credible testimony instructive here. (Jena Trial Tr. 316:4–321:21.)

As to PAH physicians, the Court finds Dr. Forfia's testimony to be somewhat[30] credible and reliable because it is "grounded in his experience, training, and specialized knowledge." *Pfizer v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 276 (D.N.J. 2006); *see also Altana Pharma AG v. Teva Pharms. USA, Inc.*, Civ. A. No. 04-2355, 2013 WL 12164773, at *2 (D.N.J. May 14, 2013) ("It is well settled that an expert may base his opinions on his experience in his specialized field." (citing *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 399–400 (3d Cir. 2003)). However, although the Court recognizes Dr. Forfia's well-respected position in the PAH medical field, the Court finds his testimony is unreliable to the extent it is offered for the assertion that PAH physicians' preferences were not affected by the lack of a subcutaneous option due to their reluctance to transition patients from Remodulin to generic treprostinil. Indeed, Dr. Forfia conceded that he did not conduct any relevant analyses or surveys on this subject. (Forfia Trial Tr. 514:10–22, 515:10–18, 516:14–517:2.) Further, a contemporaneous exhibit provided by UTC entitled "Treprostinil Injection – Sales and Marketing Update," showed that 26% of physicians were not prescribing generic treprostinil and specified it was because they were "[w]aiting for [subcutaneous]" to be offered. (DX 209.) The Court also heard credible testimony that the "incomplete launch" caused reputational harm to Sandoz akin to the reputational harm that Teva suffered following their failed launch of Flolan. (Jena Trial Tr. 314:5–18, 333:9–22.)

Regarding the payers, the Court finds that credible testimony establishes the reasonable certainty of the effect of the lack of a subcutaneous option. (Moomaw Trial Tr. 204:11–18.) For instance, the Court heard unrefuted, credible testimony that the lack of a distinction between the intravenous and subcutaneous routes of administration made it burdensome for payers to manage

[30] The Court notes: (1) Dr. Forfia's obtainment of "consulting" payments from branded pharmaceutical companies (Forfia Trial Tr. 536:16–537:25); and (2) Dr. Forfia's misleading statement in his expert report (*id.* 538:20–539:9).

the class and resulted in some payers demonstrating an unwillingness to mandate or prefer generic treprostinil. (Spina Trial Tr. 78:25–79:21; Moomaw Trial Tr. 199:16–200:10, 208:10–209:24; PX 72.) In fact, Dr. Nicholson conceded that the J-Code issue created operational challenges which made it more difficult for payers to prefer generic treprostinil. (Nicholson Trial Tr. 607:7–22.) Dr. Jena also provided credible testimony regarding the implications of documentary evidence. (Jena Trial Tr. 325:5–326:7.)

Therefore, based upon the testimony and admissible evidence presented at trial, the Court finds Sandoz has provided an appropriate method for quantifying damages. Accordingly, the Court adopts the April 2019 forecast's generic penetration rate utilized by Dr. Jena.

2. Dr. Jena's Primary Damages Model Fails to Account for the Entry of Other Generic Manufacturers in the Real World

Dr. Jena's primary damages model, which calculates $168,449,601 in damages, assumes that Sandoz would have achieved 100% of the generic market share in the subcutaneous segment. (Jena Trial Tr. 366:12–369:8.) Dr. Jena explains his decision by stating that, "[i]n the but-for world where [subcutaneous] was available in March of 2019, that is a world where I assume that the breach of contract would have only applied to [the Sandoz Parties], meaning that they would have had access to the subcutaneous cartridges." (*Id.* 295:24–296:2.) Further, the Sandoz Parties "would have been the sole supplier moving forward [sic] two years of subcutaneous cartridges." (*Id.* 296:3–4.) Dr. Jena thereafter stated, if he had calculated Sandoz's lost profits with the consideration that other generics would have entered the market in both the intravenous and subcutaneous space, "I estimate that in that scenario, where Sandoz and RareGen didn't have exclusive access to those cartridges, [subcutaneous] cartridges, and other companies could have entered after that 180 days, in that case, the lost profits would be $137 million." (*Id.* 296:11–18.)

On cross-examination, Dr. Jena acknowledged he was aware, at the time he made his

damages model, that other generic manufacturers entered into settlement agreements with UTC permitting them to market generic treprostinil in the United States.[31] (*Id.* 367:17–368:1.) Dr. Jena also clarified by stating the following during cross-examination:

> Q. Your but-for world here assumes that [UTC] would not have been required to allow other generics other than Sandoz to use the CADD-MS 3 cartridges.
>
> A. That's the correct depiction of how I construct the but-for world.
>
> . . . .
>
> Q. And your damages model assumes that none of those other generic manufacturers had entered into agreements with [UTC] that also required [UTC] not to prevent or delay their entry?
>
> A. What it assumes actually is not quite that. And I'm happy to expand, but let me pause there for you.
>
> . . . .
>
> A. The assumption of the model is whatever those agreements might have been, and I'm not sure what the details of those agreements are, is that the breach of contract would not have applied—the breach of contract claim would not have applied to Sandoz. Sandoz and RareGen would have had access to the cartridges. That's what the assumption is of the model.

[31] The parties dispute the admissibility of the settlement agreements (DX 345–47) between UTC and other generic treprostinil manufacturers. (ECF No. 492 at 68–70.) Sandoz contends the settlement agreements are inadmissible under Federal Rules of Evidence 402 and 403. (*Id.*) Sandoz's primary contention as to why the settlement agreements are inadmissible is that UTC failed to properly disclose these agreements prior to trial; specifically, "UTC never produced these materials to Sandoz until ***March 2024***—years after the close of fact discovery, years after the end of expert discovery, and just a few weeks before trial." (*Id.* at 68 (emphasis in original).) At trial, the Court admitted the settlement agreements subject to arguments to be considered at a later juncture. (Gray Trial Tr. 426:15–428:9.) Based on Dr. Jena's admission that he was aware of the settlement agreements at the time he made his damages model (Jena Trial Tr. 367:17–368:1), it may be unnecessary for the Court to resolve this admissibility dispute. Regardless, the Court in exercising its discretion finds that the settlement agreements are relevant and admissible as they were predominantly used by UTC to challenge Dr. Jena's damages analysis on cross-examination.

> Q. And your assumption, however, is that none of the other generics would have access to those CADD-MS 3 cartridges?
>
> A. Correct.
>
> Q. Okay. And if that assumption turned out to be wrong, then Sandoz could no longer be assumed to capture 100 percent of the generic subcutaneous treprostinil sales?
>
> A. That would be correct, and that's what I spoke about in my direct, that 137 [million] number you heard about, that's what it is.

(*Id.* 367:11–369:3.)

The Court is disquieted by Dr. Jena's decision not to account for what occurred in the real world in his primary damages model which arrives at a final damages calculation of $168,449,601.00. It is appropriate for a damages expert to account for real-world events when calculating but-for damages. *See Castro v. Sanofi Pasteur Inc.*, 134 F. Supp. 3d 820, 833, 840, 848–49 (D.N.J. 2015) (accepting and describing an expert's damages model in an antitrust class action which used both theories from the but-for world and real-world data for calibration purposes); *cf. Ingrao v. Goncalves*, Docket No. A-1332-10T1, 2011 WL 2306853, at *8 (N.J. Super. Ct. App. Div. June 6, 2011) (stating, in a personal injury case, "there is often an element of artificiality in constraining the admission of evidence that develops in the real world after the court-imposed discovery end date," thereby indicating real-world evidence can be supplemented with artificial evidence). Additionally, the Third Circuit has espoused a general principle that an expert's testimony on lost profits damages must be grounded in some semblance of reality. *See Advent Sys.*, 925 F.2d at 682. Applying this principle, the Court finds that application of Dr. Jena's alternative lost profits damages analysis—which takes into account other generics' entry into the

market in both the intravenous and subcutaneous space—is proper.[32] Accordingly, Sandoz's lost profits damages are reduced from $168,449,601.00 to $137,226,191.00. (DX 376 at 1–2; Jena Trial Tr. 296:8–18.)

C. Reduction of Lost Profits That Would Have Been Owed to RareGen

A "corollary" to New Jersey's rule on damages for breach of contract claims "is that the injured party should not recover expenditures which will be saved because it has been excused from further performance by the other party's breach. . . . Saved costs obviously include those which the non-breaching would otherwise have had to expend and which are avoided[.]" *Magnet Res., Inc. v. Summit MRI, Inc.*, 723 A.2d 976, 985 (N.J. Super. Ct. App. Div. 1998) (internal quotation marks and citations omitted); *see VICI Racing, LLC v. T-Mobile USA, Inc.*, 763 F.3d

[32] For similar reasons, the Court will not apply Dr. Jena's alternative damages model which calculates total damages to be $94,817,099 by incorporating the entry of other generic manufacturers and utilizing but-for generic prices. (DX 376 at 7.) Dr. Jena's primary damages model uses real-world generic prices with but-for generic penetration rates. (Jena Trial Tr. 363:24–366:7.) The real-world generic prices ranged from $45.82 after the first 180 days to $37.92 after the first year of entry, whereas the estimated generic prices from RareGen's April 2019 forecast range from $39.39 after the first 180 days and dropped by more than 50% after the first year of entry. (Jena Trial Tr. 365:7–13.) The utilization of real-world generic prices with real-world generic penetration rates represents, in Dr. Nicholson's words, "consistent economic pairing." (Nicholson Trial Tr. 598:3–9.) Conversely, the utilization of real-world generic prices with but-for generic penetration rates, represents an inconsistent economic pairing. Here, the Court does not question Dr. Jena's decision to utilize real-world generic prices, and notes that Dr. Nicholson also utilized the real-world prices. *See Advent Sys.*, 925 F.2d at 682. However, the Court does recognize that Dr. Jena's inconsistent pairing of real-world generic prices and but-for generic penetration rates may be problematic as the but-for generic penetration rate in RareGen's April 2019 forecast incorporated the price drops mentioned above. Neither party proffered a conclusive solution to this inconsistency. UTC suggests the Court should apply the but-for prices based on the price projections included in RareGen's April 2019 forecast that Dr. Jena used in alternative damages models. (ECF No. 494 at 45 (citing Jena Trial Tr. 366:2–6).) This does not appear proper to the Court as the utilization of but-for generic prices would completely contradict the pricing exhibited in the real world. Accordingly, as the Court has already provided its conclusions of law as to the propriety of Dr. Jena's applied generic penetration rate, the Court finds the more prudent approach is to simply acknowledge that the inconsistent economic pairing does not prevent the Court from arriving at lost profits damages that are reasonably certain in light of the testimony and evidence presented at trial.

273, 294 (3d Cir. 2014) (applying Delaware law and finding: "Once the loss attributable to nonperformance has been determined, a court must subtract any costs avoided as a result of the breach that are evident in the record." (citations omitted)); *cf. In re Cmty. Med. Ctr.*, 623 F.2d 864, 866 (3d Cir. 1980) ("Where profits are anticipated from the performance of an executory contract, damages in the event of a breach consist of the total amount to be received, less any expenses, excluding fixed overhead, saved by the plaintiff by not being required to complete his part of the agreement." (citations omitted)). Indeed, "[t]o permit the plaintiff to recover both lost profits and costs and expenses would result in an impermissible 'double' recovery." *Flag Serv. & Maint. v. Kirchner Truck & Equip.*, Docket No. A-2980-08T3, 2010 WL 2795376, at *6 (N.J. Super. Ct. App. Div. July 2, 2010) (citing *Gardner v. Rosecliff Realty Co.*, 124 A.2d 30, 35 (N.J. Super. Ct. App. Div. 1956)). It is the plaintiff's burden to prove that saved costs should not be deducted from lost profits damages. *See Magnet Res.*, 723 A.2d at 986–87 ("The enterprise which has incurred the relevant costs is in the best position to adduce the proof which will establish whether those costs are properly deductible from profits under the rule discussed here.").

Here, under the promotion agreement between the Sandoz Parties, RareGen was an "independent contractor" for Sandoz, and the contractual relationship "did not constitute a partnership." (PX 126 § 13.11.) Sandoz had "final decision-making authority (in its sole discretion) with respect to all RareGen activities related to" generic treprostinil. (*Id.* § 4.4.) Sandoz agreed to pay RareGen a percentage of future sales profits dependent on the amount of profits. (*Id.* § 6.3.)

The Court recognizes Sandoz did not pay RareGen a sales commission. However, payments to a contractor that increase with a higher sales volume, like here, are saved variable costs that a defendant liable for a breach of contract need not reimburse a plaintiff for because the plaintiff avoided these costs as a result of the breach. *See Tunis Bros.*, 952 F.2d at 735–36 (defining

"net profits" as "gross revenue less fixed costs, and less variable costs pegged to the number of units sold" (quoting *Coleman Motor Co. v. Chrysler Corp.*, 525 F.2d 1338, 1351 (3d Cir. 1975)); *but see Penncro Assocs., Inc. v. Sprint Spectrum L.P.*, Civ A. No. 04-2549, 2006 WL 1320252, at *18 (D. Kan. May 15, 2006), *aff'd*, 499 F.3d 1151 (10th Cir. 2007) ("[Plaintiff] will not receive a windfall if it recovers lost profits without a deduction for amounts it would have paid in increased officer compensation because the increased compensation would have flowed directly from the profits themselves, not as an additional cost incurred by [plaintiff]. The court, then, declines to deduct officer compensation as a cost of [plaintiff]'s performance."); *Conestoga Tr. v. Columbus Life Ins. Co.*, Civ. A. No. 15-152, 2016 WL 8711403, at *9 (W.D. Tex. July 29, 2016) ("[Defendant] has directed the Court to no legal authority whatsoever in support of its contention [plaintiff] has no damages because it pays all its profits to [a third party] pursuant to a [separate contract]. At best, [defendant] has marshaled some sort of equitable argument misuse of the corporate form, and the Court finds this approach unpersuasive.").[33]

Accordingly, the Court finds that reduction of the share of profits that would have been owed to RareGen—80% of net profits up to $50 million and 50% of net profits thereafter up to $500 million—from the total lost profits is warranted. However, the Court cannot properly calculate the total amount of the reduction without a clear calculation of the profits Sandoz actually made from generic treprostinil during the damages period. *See Totaro*, 921 A.2d at 1108 ("The goal of compensatory damages in a breach of contract claim is "to put the injured party in as good a position as . . . if performance had been rendered." (quoting *Donovan*, 453 A.2d at 165)

[33] The Court is not persuaded by either: (1) the trial testimony to the effect that Sandoz viewed RareGen as a partner (*see, e.g.*, Spina Trial Tr. 52:15–53:6.); or (2) the fact that Dr. Jena did not deduct the profit-share payments from his damages model because as he stated "[t]hat's just a split of profits," and not "costs that are required to generate sales." (Jena Trial Tr. 291:5–11.)

(alteration in original)). For example, if Sandoz made $25 million in net profits in the real world prior to RareGen's distribution, then 80% of the first $25 million of the lost profits in the but-for world would have been owed to RareGen; thereafter 50% of the net profits up to $500 million would have been owed to RareGen. The Court has been provided with Sandoz's total revenue from generic treprostinil during the damages period ($33,558,405.00). (DX 376.) However, Sandoz's actual profits during the damages period are unclear. The Court will not further search the record for this figure, and directs the parties to meet and confer then submit a proposed form of judgment in accordance with the parties' calculations.

D. Sandoz's Lost Profits Damages Are Not Affected by the Smiths Settlement

New Jersey's "one-satisfaction rule" provides that when a plaintiff receives satisfaction or "full compensation" of a claim from one wrongdoer, the plaintiff cannot pursue further compensation from a different wrongdoer. *See Breen v. Peck*, 146 A.2d 665, 671–72 (N.J. 1958); *see also Gelsmine v. Vignale*, 78 A.2d 602, 605 (N.J. Super. Ct. App. Div. 1951) ("[T]here can be but a single satisfaction for the same injury."); *Coleco Indus. Inc. v. Berman*, 423 F. Supp. 275, 311 (E.D. Pa. 1976), *aff'd in part*, 567 F.2d 569 (3d Cir. 1977) ("New Jersey's one-satisfaction rule . . . holds simply that if a party's claim has been satisfied, he [or she] has no further claim." (citation omitted)). "The one satisfaction rule applies to settlements as well as to satisfactions of judgments." *Williams v. Ocean Transp. Lines*, 425 F.2d 1183, 1191 (3d Cir. 1970) (citation omitted). In assessing the applicability of the one-satisfaction rule, "New Jersey cases appear to focus on the identity of damages resulting from different claims, not on the identity of the legal theories supporting the claims." *Coleco*, 423 F. Supp. at 311. Importantly, "[t]he one-satisfaction rule is equitable in nature and was designed to prevent unjust enrichment." *Theobald v. Angelos*, 208 A.2d 129, 135 (N.J. 1965) (citation omitted). "[I]t is difficult to know whether a [] claimant

has received more than full satisfaction. There is no precise measure of the amount of wrong. Even if the trial is as to damages only, successive juries would rarely make the identical appraisal." *Id.*

The Sandoz Parties settled with Smiths on November 13, 2020 (ECF No. 246), and all claims against Smiths were dismissed with prejudice (ECF No. 247). Under the settlement, Smiths paid $4.25 million to the Sandoz Parties. (PX 95 § 2.a.) It is undisputed that Sandoz received $2.125 million from this settlement. The Amended Complaint raises a claim for breach of contract (Count Seven) against UTC for its failure to comply with its obligations of the 2015 Settlement Agreement. (ECF No. 178 ¶¶ 107–21.) The Sandoz Parties sued Smiths under antitrust theories of recovery, not breach of contract. (*See generally id.*)

Although separate legal theories for recovery may be immaterial as to whether the one-satisfaction rule applies, *Coleco*, 423 F. Supp. at 311, equity demands that Sandoz's lost profits damages are not reduced by the Smiths settlement. *Glassman v. Friedel*, 243 A.3d 1268, 1286 (N.J. Super. Ct. App. Div. 2020), *aff'd*, 265 A.3d 84 (N.J. 2021) ("[W]hen the situation arises in which additional enrichment must necessarily flow to someone, the more just result is to have the person wronged receive the benefit and not a wrongdoer." (quoting *Rogers v. Spady*, 371 A.2d 285, 288 (N.J. Super. Ct. App. Div. 1977)); *see also Theobald*, 208 A.2d at 135. Sandoz's settlement with Smiths rectified separate claims and injuries compared to Sandoz's breach of contract claim raised against UTC. (*See* DX 297.) Accordingly, the Court finds the one-satisfaction rule does not apply; and therefore, Sandoz's lost profits damages under its breach of contract claim against UTC are not reduced by the settlement with Smiths.

IV. CONCLUSION

For the reasons set forth above, the Court adopts the April 2019 forecast's generic penetration rate utilized by Dr. Jena. However, the Court finds that application of Dr. Jena's

alternative lost profits damages analysis—which takes into account other generics' entry into the market in both the intravenous and subcutaneous space—is warranted. Accordingly, Sandoz's lost profits damages are reduced from $168,449,601.00 to $137,226,191.00. The Court further concludes that a reduction from $137,226,191.00 is warranted, as the share of profits owed to RareGen pursuant to the promotion agreement—80% of net profits up to $50 million and 50% of net profits thereafter up to $500 million—is a saved cost. To calculate this reduction, the parties shall consider the actual profits that were realized in Sandoz's intravenous-only launch of generic treprostinil. Finally, the Court finds Sandoz's lost profits damages are not affected by the Smiths Settlement. Counsel for the parties shall meet and confer then submit a proposed form of judgment denoting a lost profits damages amount consistent with these findings plus prejudgment interest.[34]

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE

Dated: September 6, 2024

[34] The Court is sitting in diversity and will apply New Jersey law to the issue of prejudgment interest. *Wintrust Specialty Fin. v. Pinnacle Com. Credit, Inc.*, Civ. A. No. 20-16589, 2023 WL 8664582, at *2 (D.N.J. Dec. 14, 2023) ("As an award of prejudgment interest is a procedural question of law and there is no federal law or rule governing the issue, . . . the law of the forum state in which this Court sits—New Jersey—applies here." (citing *Jarvis v. Johnson*, 668 F.2d 740, 746 (3d Cir. 1982)). The Court, in exercising its discretion, finds that prejudgment interest is warranted to properly compensate Sandoz for the lost value and use of its breach of contract damages. *Cnty. of Essex v. First Union Nat'l Bank*, 891 A.2d 600, 608 (N.J. 2006) ("[T]he award of prejudgment interest on contract and equitable claims is based on equitable principles." (citation omitted)); *Meshinsky v. Nichols Yacht Sales, Inc.*, 541 A.2d 1063, 1070 (N.J. 1988) ("Ordinarily, the trial court has the discretion to grant or deny prejudgment interest." (citing *Fasolo v. Bd. of Trs., Div. of Pensions*, 464 A.2d 1180, 1187 (N.J. Super. Ct. App. Div. 1983)); *Rova Farms Resort, Inc. v. Invs. Ins. Co. of Am.*, 323 A.2d 495, 506 (N.J. 1974) ("[P]rejudgment interest has been regarded by [New Jersey] courts as compensatory—to indemnify the plaintiff for the loss of what the monies due him would [p]resumably have earned if payment had not been refused. . . . The basic consideration is that the defendant has had the use, and the plaintiff has not, of the amount in question; and the interest factor simply covers the value of the sum awarded for the prejudgment period during which the defendant had the benefit of monies to which the plaintiff is found to have been earlier entitled." (citations omitted)). Accordingly, the parties are directed to confer and calculate the proper amount of prejudgment interest, then incorporate this amount into the proposed form of judgment.